

**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): November 23, 2020

**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.)

1180 Celebration Boulevard, Suite 103, Celebration, FL  
(Address of Principal Executive Offices)

34747  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (321) 939-3416

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KMPH	None

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 November 23, 2020, KemPharm, Inc., a Delaware corporation (the "Company"), issued a press release (the "Press Release") which provided an update to the Company's prodrug development pipeline, including the expected filing of the Investigational New Drug application for KP879 with the U.S. Food and Drug Administration prior to year-end 2020, and the introduction of a new prodrug candidate to its pipeline, KP1077. The Company is investigating KP1077 as a potential treatment for idiopathic hypersomnia, which is an underserved, orphan disease indication. In addition, the Company provided an update to its management presentation (the "Presentation") for the same.

The Press Release and the Presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

**Exhibit**

<b>No.</b>	<b>Description</b>
99.1	<a href="#">Press Release titled "KemPharm Provides Update on Development Pipeline " dated November 23, 2020.</a>
99.2	<a href="#">Presentation titled "Management Presentation" dated November 2020.</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: November 23, 2020

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer

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## KemPharm Provides Update on Development Pipeline

*IND for KP879 Expected to be Filed Before Year-End 2020; New Prodrug Candidate Added to Pipeline, Targeting Rare CNS Disease, Idiopathic Hypersomnia (IH)*

**Celebration, FL – November 23, 2020** – KemPharm, Inc. (OTCQB: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today provided an update to its prodrug development pipeline, including the expected filing of the Investigational New Drug (IND) application for KP879 with the U.S. Food and Drug Administration (FDA) prior to year-end 2020, and the introduction of a new prodrug candidate to its pipeline, KP1077. KemPharm is investigating KP1077 as a potential treatment for idiopathic hypersomnia (IH), which is an underserved, orphan disease indication.

“Our primary focus during 2020 has been advancing KP415 into and through the NDA review process with the FDA, but it has not been our sole focus,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “While we believe KP415 has the potential to be a primary value driver for KemPharm in the near future, we continue to expand our pipeline with new growth opportunities for the Company. In this regard, we are pleased to announce the discovery of our newest prodrug candidate, KP1077, and the expected filing of the KP879 IND before year-end.”

KP1077 is KemPharm’s newly developed investigational product candidate for the treatment of IH, a neurological disorder marked by significant, detrimental effects on nighttime sleep as well as daytime sleepiness/wakefulness.

KemPharm is developing KP879 as an extended-duration, agonist replacement therapy for the treatment of Stimulant Use Disorder (SUD). KP879 utilizes serdexmethylphenidate (SDX), KemPharm’s prodrug of d-methylphenidate (d-MPH). There are currently no products in the market which are designed or approved to treat SUD.

Dr. Mickle continued, “We believe that both KP879 and KP1077 showcase several important future opportunities for KemPharm. First, these product candidates may allow us entry into orphan disease indications, which are underserved, and as a result, may qualify for both Fast-Track status and Orphan Drug designation from the FDA. Second, each product candidate leverages our LAT® approach, which we believe demonstrates the versatility of the technology, and, in the case of SDX, its unique ability to serve as a product platform.”

Dr. Mickle concluded, “You are cordially invited to attend the upcoming KP415 online investor event that we are co-hosting with our partner, Corium, Inc., on December 2, 2020, beginning at 10:00 a.m. ET. Together, we plan to provide insights into the KP415 market opportunity and commercialization strategy ahead of the anticipated March 2, 2021 PDUFA date for KP415.” The Company will provide more details about how to attend the online presentations prior to the event.

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**About KemPharm:**

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT<sup>®</sup> (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT<sup>®</sup> technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. In addition, KemPharm has received FDA approval for APADAZ<sup>®</sup>, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. For more information on KemPharm and its pipeline of prodrug product candidates visit [www.kempharm.com](http://www.kempharm.com) or connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

**Caution Concerning Forward Looking Statements:**

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation our proposed development and commercial timelines, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements, including the timing of the PDUFA date and potential FDA approval of the KP415 NDA, the potential commercial launch of KP415, the potential clinical benefits of KP415 or any of the Company's product candidates, including KP879 and KP1077, the potential initiation or timeline for the development of any of our product candidates, are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm's business are described in detail in KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, KemPharm's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

**KemPharm Contacts:**

Jason Rando / Maureen McEnroe  
Tiberend Strategic Advisors, Inc.  
212-375-2665 / 2664  
[jrando@tiberend.com](mailto:jrando@tiberend.com)  
[mmcenroe@tiberend.com](mailto:mmcenroe@tiberend.com)



**KemPharm**

**Management Presentation**

**November 2020**



## Cautionary Note Regarding Presentation Information

This presentation may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation our proposed development and commercial timelines, and can be identified by the use of words such as “may,” “will,” “expect,” “project,” “estimate,” “anticipate,” “plan,” “believe,” “potential,” “should,” “continue” or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements, including the timing and probability of potential FDA approval of the KP415 NDA, the potential commercial launch of KP415, the expectations regarding continued research and development services revenue, the potential clinical benefits of KP415 or any of our other product candidates, including KP879, KP922 and KP1077, the potential initiation or timeline for the development of any of our product candidates, the potential results from the commercialization of APADAZ<sup>®</sup>, cash runway and the ability to continue as a going concern are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm’s business are described in detail in KemPharm’s Annual Report on Form 10-K for the year ended December 31, 2019, and KemPharm’s other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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: Recent Highlights

<p><b>KP415 Updates</b></p> <ul style="list-style-type: none"><li>- Held mid-cycle review meeting w/ FDA on Aug 13, affirmed PDUFA date of Mar 2, 2021, no safety issues raised at that time<ul style="list-style-type: none"><li>- Late-cycle review meeting to be held on Dec 1</li></ul></li><li>- Two additional U.S. patents governing SDX products issued, adds 5 years (2037 expiry)</li></ul>	<p><b>Q3 2020 Financial Results</b></p> <ul style="list-style-type: none"><li>- Revenue of \$1.9M from consulting services</li><li>- Total cash and investments was \$5.5M at Sep 30, 2020, decrease of \$1.1M compared to Jun 30, 2020</li><li>- Based on current operating forecast, projected cash runway extends up to the debt maturity date of Mar 31, 2021</li></ul>
<p><b>Partnership Updates</b></p> <ul style="list-style-type: none"><li>- New consultation services agreement with <b>Corium</b> for projects other than KP415 with potential revenue through Mar 2022</li><li>- Announced collaboration between <b>KVK-Tech</b> and Sure Med Compliance for APADAZ® pilot program in Alabama</li></ul>	<p><b>Improving Financial Position</b></p> <ul style="list-style-type: none"><li>- Optimized restructuring transaction(s) and subsequent potential reverse stock split could lead to re-listing on Nasdaq</li><li>- Project cash burn remains at ~\$1M/quarter</li><li>- Balance sheet restructuring process is ongoing, with multiple options under consideration</li></ul>





# KemPharm Leverages its LAT™ Prodrug Technology to Improve the Attributes of Approved Drugs in Large Markets



- 1) Select FDA-approved and widely prescribed drug for improvement, seek indications with few options or significant unmet need
- 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
  - Generates long-lived **composition-of-matter** patent protection
  - Proprietary to KemPharm and **applicable across many therapeutic areas**

## Partnered Assets – Potential For Near and Long-Term Value

Candidate	Indication	Partner	Status
<b>KP415</b> Methylphenidate ER	ADHD	Gurnet Point Capital/Corium	<ul style="list-style-type: none"> <li>• Licensed</li> <li>• PDUFA Date Mar 2, 2021</li> <li>• Approval milestone up to \$48M</li> <li>• Potential launch 2H 2021, royalties to follow</li> </ul>
<b>KP484</b> Methylphenidate ER	ADHD	Gurnet Point Capital/Corium	<ul style="list-style-type: none"> <li>• Licensed</li> <li>• Ready to enter clinical phase</li> <li>• Timing TBD with partner</li> </ul>
<b>KP879</b> Methylphenidate	Stimulant Use Disorder (SUD)	Gurnet Point Capital/Corium	<ul style="list-style-type: none"> <li>• Optioned</li> <li>• IND filing expected Q4 2020</li> <li>• Pre-clinical not needed, clinical to begin in 2021</li> <li>• Need to reach POC to begin license process</li> </ul>
<b>KP922</b> Amphetamine	ADHD	Gurnet Point Capital/Corium	<ul style="list-style-type: none"> <li>• Optioned</li> <li>• Timing TBD</li> </ul>
<b>APADAZ®</b> Hydrocodone IR	Pain	KVK Tech	<ul style="list-style-type: none"> <li>• Licensed</li> <li>• Commercial launch anticipated in Q4 2020</li> <li>• During 2021, potential for \$3.4M in m/s and reimb, plus profit share up to 50% with successful launch</li> </ul>



## Current Development Pipeline

Indication	Product Candidate	Parent Drug	Next Milestone	Potential Timing of Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	PDUFA	March 2, 2021	NA
	KP484	Methylphenidate (ER)	Initiation of Efficacy Trial	2021	2023
<b>First-in-Class Therapy</b>					
Stimulant Use Disorder (SUD)	KP879	Methylphenidate (ER)	IND Filing	4Q 2020	2024
<b>Rare CNS Diseases</b>					
Idiopathic Hypersomnia (IH)	KP1077	Undisclosed	Pre-IND Meeting	1H 2021	TBD – Exploratory Program



# KP415 and KP484

D-Methylphenidate Prodrug Products for the Treatment of ADHD



## ADHD and ER Methylphenidate Market – 2019

- ~\$17.5 billion ADHD market with prescription growth of >4% year-over-year
- The branded portion of the ADHD market was ~\$7.4B in 2019 and more than 95% of these branded prescriptions are for extended release
- Methylphenidate (MPH) accounted for approximately 20 million TRx's and \$4.9 billion in sales in 2019
- 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

Market Data Source: Symphony Health, PHAST 2019

## KP415 and KP484 Product Overviews

### KP415

- Prodrug of d-MPH (SDX) with extended release properties, co-formulated with IR d-MPH
- Potential features and benefits:
  - Once-daily dosing
  - Earlier onset, long duration
  - Lower abuse potential
  - Patient-friendly dosage form
- Potential to be first MPH product approved for pre-school ages
- No generic equivalent product
- Composition-based patents expire in 2037; potentially NCE eligible

### KP484

- Prodrug of d-MPH (SDX) with extended release properties
- Potential features and benefits
  - Once-daily dosing
  - Longer duration than other extended release ADHD products
  - Lower abuse potential
- No generic equivalent product
- Composition-based patent expires in 2037; potentially NCE eligible



## KP415 vs. Selected ER Stimulant Products for ADHD

Product Features <sup>1,2</sup>	KP415	Vyvanse®	Adderall XR®	Focalin XR®	Concerta®
<b>Parent Drug</b>	D-MPH	D-AMPH	Mixed Salts of AMPH	D-MPH	MPH
<b>Technology</b>	ER Prodrug + IR D-MPH	ER Prodrug	ER MAS	ER D-MPH	Osmotic
<b>Dosage Form</b>	Capsule	Capsule & Chewable	ER Capsule	ER Capsule	ER Tablet
<b>Onset</b>	✓✓✓	✗	--	✓✓✓	✗
<b>Duration</b>	✓✓✓	✓✓✓	--	✓	✓
<b>Reduced Drug Liking<sup>3</sup></b>	✓✓✓	✓✓	✗	✗	✓

(1) Package insert information for Vyvanse, Adderall XR, Focalin XR and Concerta

(2) Potential product features for KP415, if approved by FDA

(3) For KP415, reduced drug liking for serdexmethylphenidate prodrug component only

## Summary of KP415/KP484 Partnership Deal Terms

- Worldwide license with an affiliate of Gurnet Point Capital (GPC) announced Sept 2019; Corium is leading all commercialization activities
- Total of up to \$493M in upfront and milestone payments; plus royalties on Net Sales

Upfront cash	<ul style="list-style-type: none"> <li>– Rec'd \$10M, plus reimbursement/direct payment of \$8M of certain development costs for KP415</li> </ul>
Development costs and activities	<ul style="list-style-type: none"> <li>– Licensee covers development costs for KP415 post-approval, KP484, and if added, KP879 and KP922</li> <li>– KemPharm manages development activities</li> </ul>
Regulatory milestone payments	<ul style="list-style-type: none"> <li>– Rec'd \$5M payment at KP415 NDA acceptance</li> <li>– <b>KP415 approval milestone of up to \$48M based on label</b></li> <li>– KP484 approval milestone of \$10M</li> </ul>
Sales milestone payments	<ul style="list-style-type: none"> <li>– Payments totaling up to \$420M upon achievement of various tiers of annual U.S. Net Sales</li> </ul>
Royalty payments	<ul style="list-style-type: none"> <li>– Tiered royalty percentage on U.S. Net Sales ranging from high single digits to mid-twenties</li> <li>– Tiered royalties on ex-U.S. Net Sales ranging from low to mid-single digits percentages</li> </ul>
Option products	<ul style="list-style-type: none"> <li>– Option to license and develop KP879 and KP922</li> </ul>





## Corium, Inc – A GPC Portfolio Company

- Commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products
- Led by Perry Sternberg, President & CEO
  - 25 years of commercial experience across a wide range of therapeutic areas in diverse markets
  - Previously held dual role at Shire, Plc as Head of U.S. Commercial and Chief Commercial Officer/Head of Neuroscience
  - Oversaw seven therapeutic area business units and the launch and commercialization of multiple product franchises, including those targeting the ADHD space
- Corium's leadership team is also comprised of other executives with prior experience at Shire



## Corium, Inc. – An Expanding Relationship

- New consultation services agreement between KemPharm and Corium announced on Oct 5, 2020
  - Agreement encompasses product development and regulatory activities for certain current and potential future products in Corium's portfolio
  - New activities are above and beyond KemPharm's ongoing commercial support activities for KP415
- Combined with ongoing revenues from ongoing KP415 commercial support, expanded relationship provides for KemPharm to receive service fees of up to **\$15.6M** through Mar 31, 2022
  - Extends related revenue stream more than a year past the KP415 PDUFA date; possibly longer if extended



## 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 64% of total TRx<sup>1,2, 3</sup>
- In 2019, the adult<sup>3</sup> ADHD market has grown at 5% vs. 1% for the pediatric ADHD market compared to the previous year<sup>1</sup>
- Vyvanse<sup>®</sup>, the ADHD product known for its duration and abuse deterrent features has seen significant growth in the adult<sup>3</sup> market averaging 15% year-over-year growth since 2010<sup>1</sup>
- Shire's Mydayis<sup>®</sup> was recently approved as a super long-acting product in the amphetamine category (2 to 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

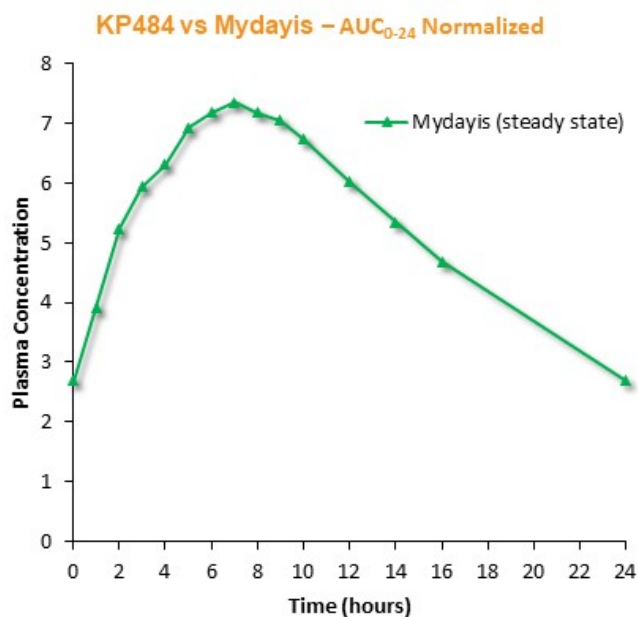
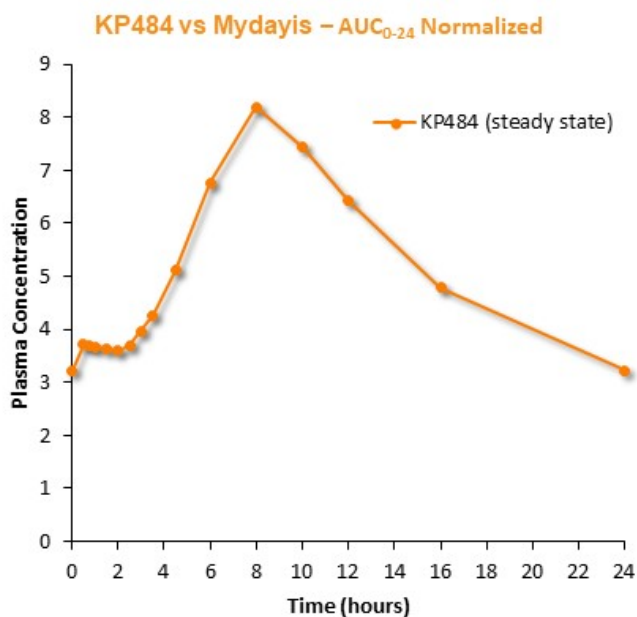
1. Symphony Health, PHAST 2009-2019

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

3. Patients aged 17+; Unknown ages were excluded



# 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.



## KP415 Updates

- Held KP415 NDA mid-cycle review meeting with FDA on Aug 13, 2020
  - FDA re-affirmed KP415 PDUFA date of Mar 2, 2021, no substantive issues or safety concerns were raised
  - Late-cycle review meeting to be held on Dec 1, 2020
- Corium, Inc. is leading all commercial activities for KP415
  - Corium continues to build out its team and its KP415 commercial launch plan; manufacturing validation underway
  - If approved, target launch date for KP415 in 2H 2021
  - KemPharm and Corium to co-host analyst/investor call to provide overview of commercial plans and market dynamics; date to be announced soon



# KP879

## Agonist Replacement Therapy for the Treatment of Stimulant Use Disorder (SUD)



## Stimulant Use Disorder (SUD)

- Stimulant Use Disorder (SUD) is broadly defined as the abuse or misuse of cocaine, methamphetamine, or other stimulants
- Although there are therapies for opioid addiction (buprenorphine, methadone), there are currently no approved treatments for SUD
- Studies with agonist replacement therapies have shown promising data for treating SUD

### U.S. Prevalence of Stimulant Abuse in 2016

Stimulant	Abuse Reported In Last 30 Days (% of US Population >12 years)
Prescription Stimulants	1,700,000 (0.63%)
Cocaine <sup>a</sup>	1,900,000 (0.71%)
Methamphetamine <sup>b</sup>	~700,000 (0.25%)
<b>Total:</b>	<b>4,300,000 (1.59%)</b>

<sup>a</sup> includes crack cocaine

<sup>b</sup> includes only illicitly manufactured methamphetamine

Source: Substance Abuse and Mental Health Services Administration. (2017).  
HHS Publication No. SMA 17-5044, NSDUH Series H-52.

## KP879 for the Treatment of SUD

- Potential KP879 features and benefits:
  - Stand-alone formulation of serdexmethylphenidate (SDX)
  - Releases d-methylphenidate (d-MPH), a dopamine reuptake inhibitor (similar pharmacology as abused stimulants)
  - Very gradual onset of blood concentrations of released d-MPH followed by sustained release
  - Low oral, IN, and IV abuse potential
- Focus of initial clinical studies
  - High dose PK
  - High dose safety
  - Effect size in different treatment populations
- May qualify for FDA fast track, breakthrough therapy and/or priority review
- May qualify for orphan designation depending on exact indication and target population





**KP1077**

**For the Treatment of Idiopathic Hypersomnia (IH)**



## Idiopathic Hypersomnia (IH)

- There are no approved therapies for IH
- Narcolepsy treatments have commonly been used for treating IH symptoms
  - GHB/sodium oxybate for improved sleep
  - Stimulants for Excessive Daytime Sleepiness (EDS)
    - Methylphenidate remains the most commonly used stimulant for IH
    - Amphetamine
    - Modafinil
- Unmet needs are focused on symptom control
  - No 16-hour product available for EDS symptom control
  - PRN (as needed) utilization of IR methylphenidate is very typical for “break-through” sleepiness



## KP1077 Product Candidate Overview

- Once daily dosing
- Potential features and benefits
  - Single dose allows for symptom control up to 16 hours
  - Still allows for PRN stimulant use for “break-through” sleepiness
- Orphan drug designation potential
  - Fast-track eligible
  - Break-through designation eligible
  - Pediatric rare disease potential
- No generic equivalent
- Composition-of-matter based patents expire in 2037; additional applications may extend past that time



**APADAZ<sup>®</sup>**

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



## APADAZ® Overview

- First FDA-approved prodrug of hydrocodone (benzhydrocodone) combined with acetaminophen with differentiated label and long-lived patents
- Licensed to KVK-Tech, Inc.
  - KemPharm eligible to receive up to \$3.4M in initial payments and reimbursements, plus sales milestone payments of up to \$53M
  - Net profit share of up to 50% between KemPharm and KVK
- The commercial payor category accounted for 1.3B HC/APAP tablets, or 37% of a total of 3.5 billion HC/APAP tablets utilized in the U.S. in 2019<sup>1</sup>
- Current environment for opioids is difficult due to ongoing litigation related to past opioid marketing; progress continues
- Sure Med and KVK collaborating on a patient/provider support program - Perspectives in Care® - to provide education to physicians, pharmacies, and patients regarding responsible opioid therapy

1. Symphony Health PHAST: 2019



# Prodrug Discovery Collaboration



## Deerfield and KemPharm Prodrug Discovery Collaboration

- In connection with our December 2019 debt restructuring, we have agreed to collaborate on a potential prodrug discovery effort with Deerfield
- Deerfield, or its affiliates, may identify up to two compounds with applications for new disease indications, and KemPharm will utilize its proprietary prodrug technology to potentially discover acceptable new product candidates for development
- Potentially create new prodrugs designed to:
  - Improve profile of drug candidate
  - Generate long-lived composition-of-matter patents
  - Address unmet patient needs
- If successful, KemPharm and Deerfield, or its affiliate, may further collaborate to develop the product candidate(s) subject to mutually agreeable terms and conditions



# Financial Update





## Q3 2020 Financial Results

- Revenue and Net Income (Loss)
  - Revenue of \$1.9M, comprised of services revenue under the Corium consulting arrangement, compared to Q2 2020 service revenue of \$1.9M
  - Q3 2020 is the fifth sequential quarter of services revenue
  - Net loss of (\$3.0M), or (\$0.04) per basic and diluted share, compared to net income of \$3.1M, or \$0.09 per basic share and \$0.06 per diluted share for Q3 2019
- Expense
  - Q3 2020 operating loss of (\$1.2M), which is a change of \$4.4M compared to net operating income of \$3.2M in Q3 2019, primarily driven by a decrease in revenue of \$9.5M, and partially offset by decreases in operating expenses of \$5.1M
  - R&D expenses were \$1.7M, a 53% reduction compared to Q3 2019
  - G&A expenses were \$1.4M, a 60% reduction compared to Q3 2019



## Q3 2020 Balance Sheet Update

- As of Sep 30, 2020, total cash<sup>1</sup> was \$5.5M, a decrease of \$1.1M compared to Jun 30, 2020; forecasted cash burn rate of ~\$1M/quarter
  - Based on operating forecast, expected revenues and existing resources, cash runway expected to up to the debt maturity date of Mar 31, 2021
- Total debt, net, of \$65.9M at Sep 30, 2020, vs. \$67.3M at Jun 30, 2020
  - Reduction of \$1.4M due to Deerfield exchanges of \$3.1M during Q3 2020, offset by interest added to principal of \$1.2M and amortization of debt discount and issuance costs of \$0.6M
- As of Sep 30, 2020, stockholders' deficit was (\$62.3M)
- As of Oct 28, 2020, 72,544,837 common shares outstanding

<sup>1</sup> - Includes cash, cash equivalents and restricted cash.



## Improving Financial Position

- Phase 2 of debt restructuring remains one of our highest priorities; goal to complete prior to the KP415 PDUFA date
- Continue to work with our financial advisors to determine the best pathway to restructure the debt and optimize the cost of capital/dilution; options include:
  - Debt to equity conversion
  - New corporate debt with extended maturity
  - Debt repayment from potential KP415 milestone, secondary offering, or royalty financing
- Likely outcome will be a combination of these options; the cost of capital will be dynamic approaching KP415 catalysts and Mar 31, 2021 debt maturity
- A secondary goal of the process is to address our current stockholder's deficit and be positioned to meet the initial listing requirements for re-listing on the Nasdaq



## KemPharm: Next Steps and Outlook

<b>KP415 NDA</b> <ul style="list-style-type: none"><li>- FDA has set KP415 PDUFA date of Mar 2, 2021</li><li>- KP415 Late-Cycle Review meeting with FDA scheduled for Dec 1, 2020</li><li>- KP415 approval milestones up to \$48M</li></ul>	<b>Improved Financial Position</b> <ul style="list-style-type: none"><li>- Based on current operating forecast, projected cash runway extends up to the debt maturity date of Mar 31, 2021</li><li>- Expanded services revenue and careful expense management remains in focus</li><li>- Debt restructuring process active, still potential to address pre-PDUFA</li></ul>
<b>KP415 Commercial Progress</b> <ul style="list-style-type: none"><li>- KemPharm working with Corium on commercial supply for potential 2H 2021 launch</li><li>- Corium and KemPharm to provide KP415 commercial and ADHD market update; date to be announced soon</li></ul>	<b>Beyond KP415</b> <ul style="list-style-type: none"><li>- Expanded Corium services agreement adds additional revenue</li><li>- Actively preparing KP879 IND for submission to FDA</li><li>- KVK-Tech/Sure Med collaboration for APADAZ, Perspectives in Care program set to launch on Dec 1, 2020 in Alabama</li></ul>





**KemPharm**

**Leveraging our LAT™ Prodrug Technology  
to Create Long-Term Value**

For additional information please contact:

**Maureen McEnroe**

[mmcenroe@tiberend.com](mailto:mmcenroe@tiberend.com)