



KemPharm

Management Presentation

December 2020

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KemPharm: Recent Highlights

KP415 Updates

- Held late-cycle review meeting w/ FDA on Dec 1, affirmed PDUFA date of Mar 2, 2021, no safety or efficacy issues raised at that time
- Next step is confidential review/negotiation of draft label
- Two additional U.S. patents governing SDX products issued, adds 5 years (2037 expiry)

Q3 2020 Financial Results

- Revenue of \$1.9M from consulting services
- Total cash and investments was \$5.5M at Sep 30, 2020, decrease of \$1.1M compared to Jun 30, 2020
- Based on current operating forecast, projected cash runway extends up to the debt maturity date of Mar 31, 2021

Partnership Updates

- Consultation services agreement with **Corium** for projects other than KP415 with potential revenue through Mar 2022
- Announced collaboration between **KVK-Tech** and Sure Med Compliance for APADAZ® pilot program in Alabama, launched Dec 1

Improving Financial Position

- Optimized restructuring transaction(s) and subsequent potential reverse stock split could lead to re-listing on Nasdaq
- Project cash burn remains at ~\$1M/quarter
- Balance sheet restructuring process is ongoing, with multiple options under consideration



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



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
First-in-Class Therapy					
Stimulant Use Disorder (SUD)	KP879	Methylphenidate (ER)	IND Filing	4Q 2020	2024
Rare CNS Diseases					
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 ^{1,2}	KP415	Vyvanse®	Adderall XR®	Focalin XR®	Concerta®
Parent Drug	D-MPH	D-AMPH	Mixed Salts of AMPH	D-MPH	MPH
Technology	ER Prodrug + IR D-MPH	ER Prodrug	ER MAS	ER D-MPH	Osmotic
Dosage Form	Capsule	Capsule & Chewable	ER Capsule	ER Capsule	ER Tablet
Onset	✓✓✓	✗	--	✓✓✓	✗
Duration	✓✓✓	✓✓✓	--	✓	✓
Reduced Drug Liking ³	✓✓✓	✓✓	✗	✗	✓

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

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

- 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

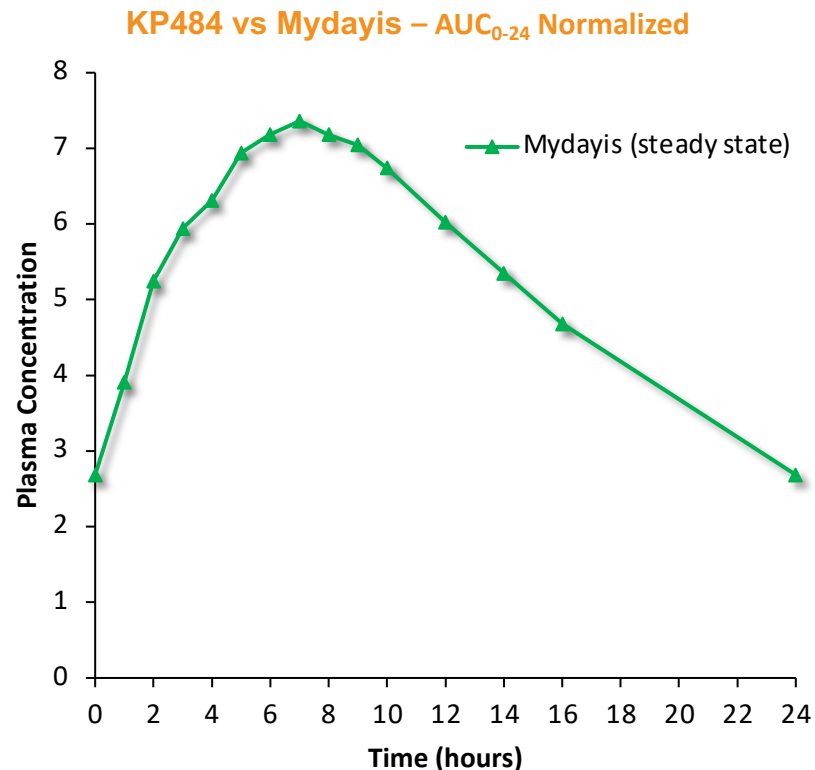
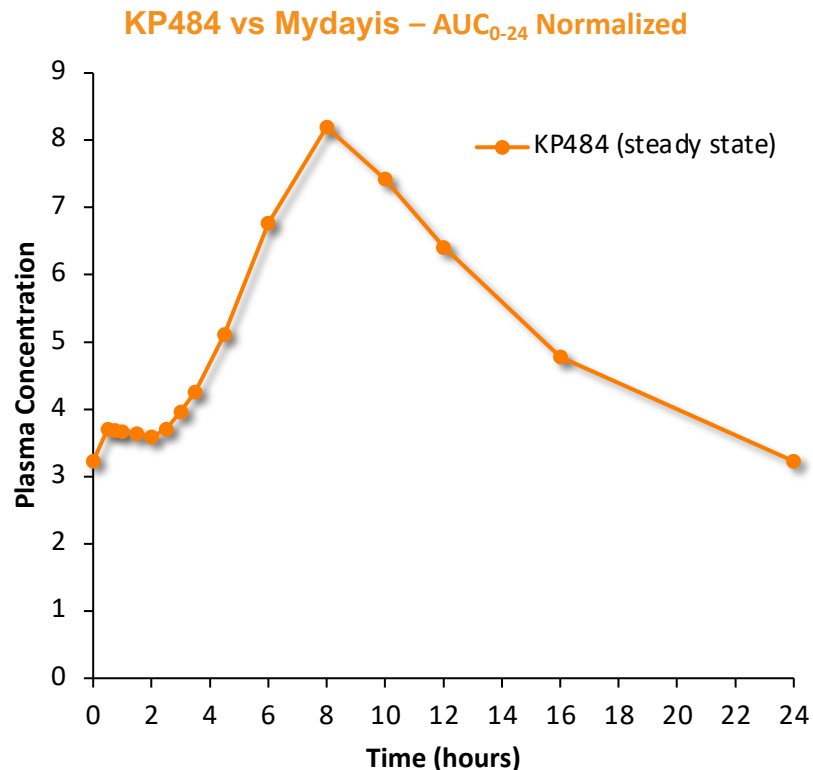
- Over 4% of U.S. adults, or approximately 10.5 million adults have ADHD and are now the largest part of the ADHD market, comprising 64% of total TRx^{1,2, 3}
- In 2019, the adult³ ADHD market has grown at 5% vs. 1% for the pediatric ADHD market compared to the previous year¹
- Vyvanse[®], the ADHD product known for its duration and abuse deterrent features has seen significant growth in the adult³ market averaging 15% year-over-year growth since 2010¹
- Shire's Mydayis[®] was recently approved as a super long-acting product in the amphetamine category (2 to16 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. Mydayis¹



Disclaimer: Mydayis steady-state plasma concentrations were modeled based on Mydayis single-dose data¹ and were normalized so that the mean AUC₀₋₂₄/C_{max} for d-amphetamine released from Mydayis matches the mean AUC₀₋₂₄/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.

KP415 Updates

- Held KP415 NDA late-cycle review meeting with FDA on Dec 1, 2020
 - FDA re-affirmed KP415 PDUFA date of Mar 2, 2021, no safety or efficacy issues were raised
 - Next step is confidential review/negotiation of draft label
- 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 co-hosted analyst/investor call on Dec 2, providing an overview of commercial plans and market dynamics
 - Webcast link: [KP415 Market Opportunity and Commercialization Strategy | KemPharm](#)



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^a	1,900,000 (0.71%)
Methamphetamine^b	~700,000 (0.25%)
Total:	4,300,000 (1.59%)

^a includes crack cocaine

^b 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[®]

**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 2019¹
- 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
- Commercial launch began Dec 1, 2020

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 cash¹ 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

¹ - 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

KP415 NDA

- FDA has set KP415 PDUFA date of Mar 2, 2021
- Looking ahead to next phase – confidential review/negotiation of draft label
- KP415 approval milestones up to \$48M

Improved Financial Position

- Based on current operating forecast, projected cash runway extends up to the debt maturity date of Mar 31, 2021
- Expanded services revenue and careful expense management remains in focus
- Debt restructuring process active, still potential to address pre-PDUFA

KP415 Commercial Progress

- KemPharm working with Corium on commercial supply for potential 2H 2021 launch
- Corium continues commercial preparations, as detailed in recent webcast held on Dec 1

Beyond KP415

- Expanded Corium services agreement adds additional revenue
- Actively preparing KP879 IND for submission to FDA
- KVK-Tech/Sure Med collaboration for APADAZ, Perspectives in Care program launched in Alabama on Dec 1, 2020





KemPharm

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

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