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): December 6, 2018

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.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL		**34747**
(Address of Principal Executive Offices)		**(Zip Code)**

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

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 December 6, 2018, Travis C. Mickle, the president and chief executive officer of KemPharm, Inc., or the Company, will present live at VirtualInvestorConferences.com on, among other things, the Company's product pipeline, co-lead clinical product candidates KP415 and KP484, both based on a prodrug of methylphenidate, or serdexmethylphenidate, and for the treatment of attention-deficit hyperactivity disorder, KP879, a stand-alone formulation of serdexmethylphenidate for the treatment of stimulant use disorder and U.S. Food and Drug Administration approved product, APADAZ®, 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	Presentation titled "Management Presentation" dated December 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KemPharm, Inc.

Date: December 6, 2018

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

Exhibit 99.1

Management Presentation

December 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 November 9, 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 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

2) Chemically modify approved drug using a **ligand** that is **GRAS or demonstrated to be safe** to create a **new prodrug**

3) Following ingestion, normal human metabolic processes cleave the ligand from the prodrug and **release the active drug**

- Generates long-lived **composition-of-matter** patent protection
- Proprietary to KemPharm and **applicable across many 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
SUD	KP879	Methylphenidate (ER)	Preclinical	IND Submission	TBD
PAIN	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
	KP606/IR	Oxycodone	Preclinical	Preclinical Development	TBD
	KP746	Oxymorphone	Preclinical	Preclinical Development	TBD

* NDA timing is contingent upon status of Apadaz commercialization efforts

Pursuing Multiple Paths to Create Long-Term Value

- Leveraging full potential of KemPharm's LAT™ prodrug technology
  - Conventional pharma partnerships for internally developed candidates
    - KP415 and KP484 partnership opportunities
  - Joint venture or collaboration with profit sharing
    - KVK license for APADAZ®
  - Prodrug technology partnerships at various stages of development
    - twoXAR
    - Genco
  - Technology and manufacturing partnerships
    - Acura – Aversion technology
    - Johnson Matthey – benzhydrocodone risk sharing development partnership

Prodrug New Product Development Partnering

- Strategy to potentially leverage KemPharm's proprietary LAT™ Platform Technology through prodrug technology 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

KemPharm Prodrug Technology Collaboration with twoXAR

- Technology collaboration announced on October 23, 2018 to develop prodrug-based therapies for multiple therapeutic areas outside of KemPharm's product focus and core expertise
- Combines KemPharm's LAT™ technology to potentially create new prodrugs with twoXAR's artificial intelligence (AI)-based technology
- twoXAR investors include SoftBank Ventures, the Andreessen Horowitz Bio Fund, OS Fund, CLI Ventures, and the Stanford-StartX Fund
- Potentially create new prodrugs designed to:
  - Improve profile of drug candidate
  - Generate long-lived composition-of-matter patents
  - Address unmet patient needs
- Under this agreement, KemPharm will begin initial research to discover a prodrug product candidate for Novoxar, a wholly-owned subsidiary of twoXAR
  - KemPharm eligible to receive license fees, milestone payments and royalties on commercial sales of developed product(s)

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 2011-2017

Selected ER Stimulant Products for ADHD

Brand Name Active Ingredient	Sponsor	Dosage Form (1)	Strengths (1)	Features (1)	Reduced Drug Liking (1)
Vyvanse® (lisdexamfetamine)	Shire	Capsule & Chewable	10, 20, 30, 40, 50, 60 & 70 (cap only) mg	• Prodrug of d-amphetamine • Ages: 6 years and older • Onset: 1.5 hours • Duration: 13 hours • Indicated for binge eating disorder	**Some Difference**
Adderall XR® (mixed salts of AMPH)	Shire	ER Capsule	5, 10, 15, 20, 25 & 30 mg	• Comprised of both L-AMPH & D-AMPH • Ages: 6 years and older • Extended release profile	No
Focalin XR® (dexmethylphenidate)	Novartis	ER Capsule	5, 10, 15, 20, 25, 30, 35 & 40 mg	• Ages: 6 years and older • Onset: 0.5 hours • Duration: 12 hours	No
Concerta® (methylphenidate)	Janssen	ER Tablet	18, 27, 36 & 54 mg	• Ages: 6 years to 65 years • Onset: 2 hours • Duration: 12 hours	**Small Difference**

(1) Package insert information

Selected ER Stimulant Products for ADHD (Cont'd)

Brand Name Active Ingredient	2017 TRx's (1)	2017 Sales (1)	2017 WAC Unit Price (2)	2017 Plan Approval Rate (1)	2017 Avg. Patient Out-of-Pocket Expense (1)
Vyvanse® (lisdexamfetamine)	11.6MM	$3.3B	40mg: $9.02	94%	$41.65
Adderall XR® (mixed salts of AMPH)	3.6MM	$895MM	20mg: $7.12	95%	$24.04
Focalin XR® (dexmethylphenidate)	964K	$352MM	20mg: $11.90	94%	$26.93
Concerta® (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, or SDX) 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
- Potential to be first MPH product approved for pre-school ages (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

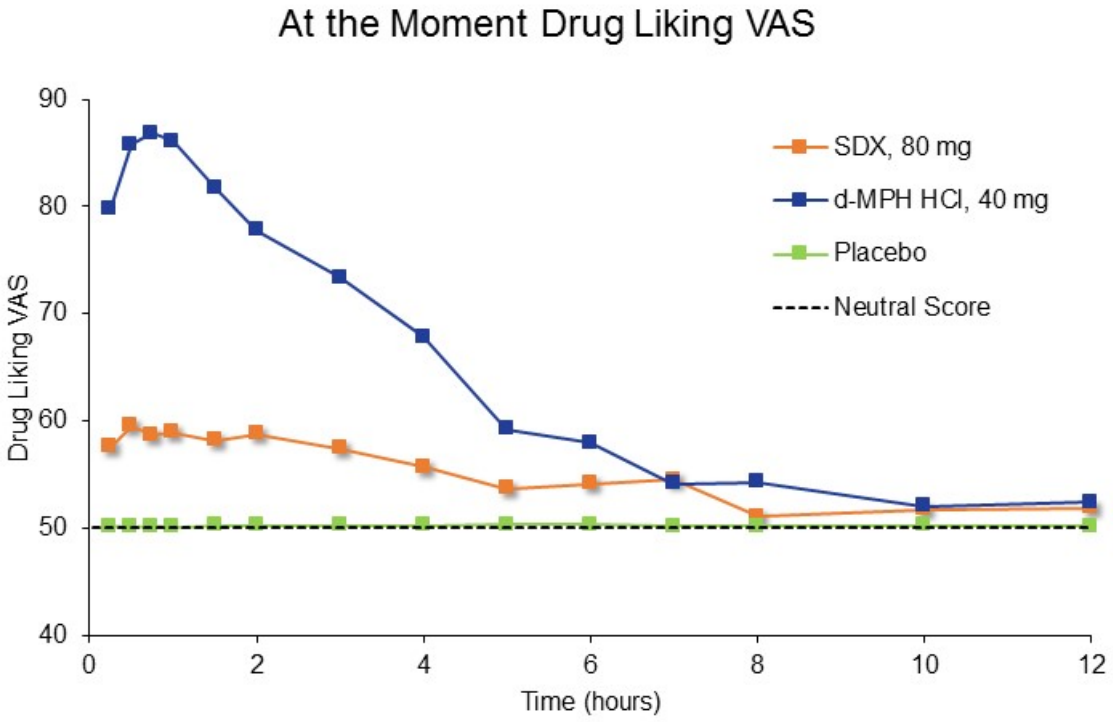
KP415.E01 Pivotal Efficacy Trial Summary

- KP415.E01 efficacy trial met its primary endpoint
- Secondary endpoints of SKAMP-C, PERMP-A and PERMP-C, as measured over time, support a 30-minute onset of effect with duration up to 13 hours
- Secondary endpoint of morning and evening behaviors, WREMB-R, as rated by parents are supportive of a 30-minute onset of effect with duration up to 13 hours
- 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®, Concerta® and Focalin XR®

KP415 Prodrug (SDX) Human Abuse Potential Trials Summary

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

KP415 Prodrug (SDX) At-the-Moment Drug Liking After Intranasal Administration vs. D-Methylphenidate



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

The Adult ADHD Market

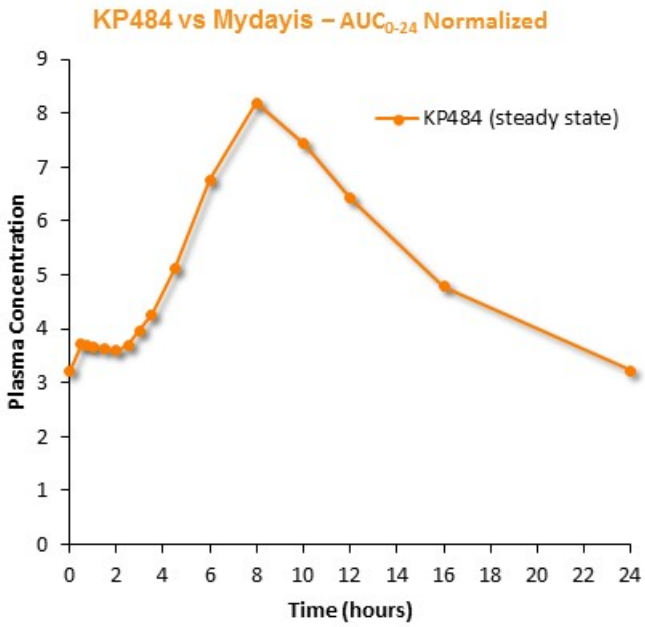
- Over 4% of U.S. adults, or approximately 10.5 million adults have ADHD and are now the largest part of the ADHD market, comprising 53% of total TRx[1,2]
- The adult ADHD market has grown at ~11% per year on average vs. 4% for the pediatric ADHD market for the last several years[1]
- Vyvanse®, the ADHD 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[1]
- Shire's Mydayis® 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

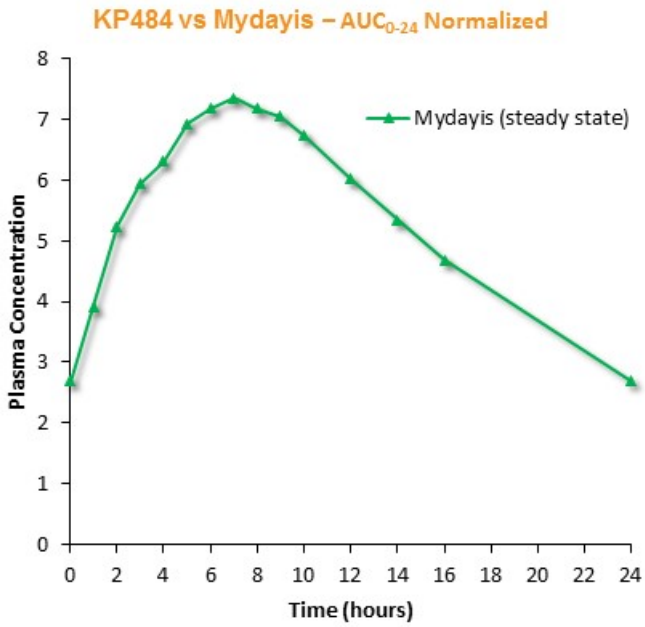
1. Symphony Health, PHAST 2011-2017
2. Ronald C. Kessler et al. (April 2006). The Prevalence and Correlates of Adult ADHD in the United States: Results From the National Comorbidity Survey Replication, American Journal of Psychiatry 163(5):71

KP484 Product Overview

- Prodrug of d-MPH (serdexmethylphenidate, or SDX) 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®[1]





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.

KP879

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

Stimulant Use Disorder (SUD)

- Stimulant Use Disorder (SUD) is 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
- A number of acute and long-term toxicities associated with SUD, most related to cardiovascular effects and chronic constriction of blood vessels

Stimulant Use Disorder (SUD)

- In a 2016 study, approximately 4.3 million Americans over the age of 12 reported stimulant abuse in the last 30 days
- In the same study, approximately 2.1 million Americans over the age of 12 had SUD (defined as meeting DSM-IV criteria for stimulant abuse or dependence) diagnosed in the last 12 months

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]	667,000 (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

- KP879 properties:
  - Stand-alone formulation of serdexmethylphenidate (SDX)
  - Releases d-methylphenidate, a dopamine reuptake inhibitor (similar pharmacology as abused stimulant drugs)
  - Very gradual initial PK with long release
  - Low oral, IN, and IV abuse potential
- KP879 pharmacokinetic profile is optimal for successful treatment of SUD
  - Gradual initial PK: should reduce euphoria and abuse-related effects
  - Long release: should allow high exposure with “smooth” profile
- KP879 pharmacodynamic profile is optimal for successful treatment of SUD
  - Treatment itself should have a low potential for abuse

Apadaz®

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® Commercial License Agreement with KVK

- As announced on October 30, 2018, KVK is granted the exclusive right for all commercial, manufacturing, packaging and distribution activities for APADAZ in the U.S. and will be responsible for regulatory and commercialization-related expenses
- KVK is a private company founded in 2004 and is one of the largest controlled substance manufacturers and distributors in the U.S.
- KemPharm eligible to receive up to an estimated $3.4 million in pre-launch payments and cost reimbursements, including a $2.0 million milestone payment upon initial formulary adoption of APADAZ
- KemPharm has the potential to receive an aggregate of up to $53 million in additional milestone payments tied to specified net sales levels
- Net profit share of up to 50% between KemPharm and KVK
- Responsibility for API costs and other materials for manufacturing, validation batches, inventory investments and other launch-specific costs shifted to KVK

APADAZ® Commercialization Strategy

KVK is expected to continue the same strategy for commercializing APADAZ; approach not expected to require the establishment of a large field sales force

Non-traditional PBM and MCO Partnerships

- Pre and post-launch activities include outreach and plan adoption by pharmacy benefit managers (PBM's), managed care organizations (MCO's) and integrated delivery networks (IDN's) for exclusive utilization of APADAZ as an alternative to currently available hydrocodone/acetaminophen products.
- Offer price parity with available generic products in exchange for a preferred formulary position, including most favorable co-pay where possible
- Utilize existing communication systems among PBMs and MCOs and employ novel approaches for outreach to build awareness
- Launch to initially focus on regional "pilots" within a variety of payer types (i.e. commercial, Medicaid, etc.) as early as 2H 2019

Financial Update

Q3 2018 Financial Results

- Q3 2018 net loss of $15.1 million, or $0.94 per basic and diluted share, vs. Q3 2017 net loss of $10.0 million, or $0.68 per basic and diluted share
  - Net loss for Q3 2018 was primarily due to loss from operations of $18.0 million and net interest expense and other items of $1.6 million, partially offset by non-cash fair value adjustment income of $4.5 million
  - Loss from operations increased to $18.0 million for Q3 2018 compared to $9.6 million for Q3 2017, primarily due to an increase of $7.0 million in research and development expenses and severance expense of $1.6 million, partially offset by a decrease of $0.3 million in general and administrative expenses
- As of September 30, 2018, total cash and investments[1] were $14.1 million, which was a decrease of $15.2 million compared to June 30, 2018
- Pro forma total cash and investments[1] post-offering were approx. $37.3M
- Based on the current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements into, but not through, Q3 2019

1 - Includes cash, cash equivalents, restricted cash, and marketable securities

Conclusion

KemPharm Expected Milestones

Product	Event	Date	
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	✓
APADAZ®	Secure Commercial Partnership	2H 2018	✓
KP415 / KP484	Secure Strategic Partnership	2H 2018	
KP415	NDA Submission	Q1 2019	
KP484	Pivotal Efficacy Study Initiation	2019	
KP484	Pivotal Efficacy Study Results	2019	
APADAZ®	Commercial Launch	2H 2019	
KP484	NDA Submission	1H 2020	

KemPharm's Next Steps

- NDA's for KP415 and KP484 on track for submission in Q1 2019 and 1H 2020, respectively
- Strategic partnering discussions for KP415 and KP484 continue based on:
  - Significant, near-term ADHD prodrug commercial opportunity
  - Differentiated onset and duration efficacy profile
  - Differentiated oral, IV and IN HAP data for SDX
  - Long patent life and potential NCE status
- Goal to announce the terms of a strategic partnership for KP415 and KP484 before the end of 2018
- Accelerate preparation for anticipated 2H 2019 APADAZ® commercial launch:
  - Begin technology and regulatory transfers (NDA) to KVK
  - Support KVK's initiation of validation batches in advance of commercial launch
  - Support KVK's efforts to initiate regional pilot launches as early as 2H 2019

KemPharm

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

For additional information please contact:
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