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): August 9, 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.)**
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 2.02 Results of Operations and Financial Condition.

On August 9, 2018, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended June 30, 2018, as well as information regarding a conference call and live audio webcast with slide presentation to discuss these corporate and financial results. A copy of the press release and presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and presentation furnished as Exhibits 99.1 and 99.2, respectively, 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 KemPharm’s filings under the Securities Act of 1933, as amended, or 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	Press Release titled “KemPharm, Inc. Reports Second Quarter 2018 Results” dated August 9, 2018.
99.2	Presentation titled "Q2 2018 Results" dated August 9, 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: August 9, 2018

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

EXHIBIT 99.1

KemPharm, Inc. Reports Second Quarter 2018 Results

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today at 4:30 p.m. ET

Development Highlights:

- Announced top line results from KP415.E01 efficacy and safety trial in children with ADHD
- Announced top line results from intravenous human abuse potential trial with KP415 Prodrug (KP415.A03)

Financial Highlights:

- Net loss of $0.65 per basic share and $0.91 per diluted share for the quarter ended June 30, 2018, compared to net loss of $0.44 per basic and diluted share for the quarter ended June 30, 2017
- Total cash and security-related amounts were $29.3 million at June 30, 2018

Coralville, IA – August 9, 2018 – KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs today reported its corporate and financial results for the second quarter ended June 30, 2018, including an update on clinical development events related to its prodrug development pipeline.

“The second quarter was highlighted by important advances involving our ADHD prodrug portfolio and our co-lead product candidate, KP415, including top line data from the efficacy and safety trial of KP415 (KP415.E01) and top line data from the intravenous (KP415.A03) human abuse potential trial with our KP415 prodrug (serdexmethylphenidate),” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “In summary, the KP415.E01 trial met the pre-specified primary and secondary efficacy endpoints, and we believe the totality of this data indicates an overall treatment effect of KP415 consistent with a 30-minute onset and 13-hour duration. Similarly, we were very pleased with the data from the KP415.A03 study, in which we observed that serdexmethylphenidate was not readily converted to the active d-methylphenidate when injected, demonstrating the potential of our prodrug to inhibit a common route of methylphenidate abuse.”

“We believe the results from these two studies suggest that KP415 offers the potential to be a differentiated methylphenidate product that is able to address key unmet needs in ADHD treatment, including early onset of action, duration of therapy and lower abuse potential,” Mickle continued. “With these milestones achieved, and with data forthcoming from the oral and intranasal human abuse potential studies of serdexmethylphenidate, we remain well positioned to file a potential New Drug Application (NDA) for KP415 in early 2019.”

Q2 2018 Financial Results:

For the quarter ended June 30, 2018, KemPharm's reported net loss was $10.0 million, or $0.65 per basic share and $0.91 per diluted share, compared to a net loss of $6.5 million, or $0.44 per basic and diluted share for the same period in 2017. Net loss for Q2 2018 was driven primarily by a 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 from $8.2 million in Q2 2017 to $13.9 million in Q2 2018, which was primarily due to an increase of $5.8 million 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 amounts, which is comprised of cash, cash equivalents, restricted cash, marketable securities and trade date receivables was $29.3 million, which was a decrease of $7.9 million compared to March 31, 2018.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation on Thursday, August 9, 2018, at 4:30 p.m. ET, to discuss its corporate and financial results for the second quarter of 2018. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 5597261

An audio webcast with slide presentation will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available for 90 days beginning later today, August 9, 2018, at approximately 5:30 p.m., ET.

Recent and Q2 2018 Activities:

- **Announced Top Line Results from KP415.E01 Efficacy and Safety Trial in Children With ADHD**

  On July 9, 2018, KemPharm announced top line results from a pivotal efficacy and safety clinical trial of KP415. Results from the trial (KP415.E01) indicated that KP415 successfully met the primary efficacy endpoint in patients with attention deficit/hyperactivity disorder (ADHD) between the ages of 6 and 12 years. The trial was a multicenter, randomized, parallel, double-blind, placebo-controlled analog laboratory classroom clinical trial in 150 children aged 6-12 years old with a diagnosis of ADHD to assess the efficacy and safety of KP415. Subjects who received KP415 met the trial's primary and secondary efficacy endpoints, showing statistically significant improvement on both the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) and the Permanent Product Measure of Performance (PERMP) scale.

- **Announced Topline Results from an Intravenous Human Abuse Potential Trial with KP415 Prodrug**

  On May 10, 2018, KemPharm announced topline results from the first of three human abuse potential trials to be conducted with the prodrug contained in both KP415 and KP484 (serdexmethylphenidate). This single-center study (KP415.A03) was designed to measure the pharmacokinetics and pharmacodynamic effects of serdexmethylphenidate, d-methylphenidate hydrochloride and placebo after intravenous (IV) administration in recreational stimulant users. Serdexmethylphenidate and d-methylphenidate hydrochloride were dosed at equimolar (equivalent) levels. Serdexmethylphenidate demonstrated statistically significant differences compared to d-methylphenidate hydrochloride in the primary endpoint, maximal Drug Liking (Emax), and no statistical difference compared to placebo. Secondary endpoints including Emax of Overall Drug Liking, Feeling High, and Good Effects were also significantly reduced for serdexmethylphenidate compared to d-methylphenidate hydrochloride, and similar for serdexmethylphenidate compared to placebo. Additionally, Emax of Take Drug Again was statistically lower for serdexmethylphenidate compared to d-methylphenidate hydrochloride. Collectively, these findings indicate that IV administration of the serdexmethylphenidate resulted in effects that were statistically similar to placebo as measured by multiple endpoints that are commonly used to assess human abuse potential.

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™ (Ligand Activated Therapy) platform technology. KemPharm utilizes its proprietary LAT platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of ADHD, pain and other central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release/effect profiles for the treatment of ADHD. In addition, KemPharm has received FDA approval for APADAZ®, an immediate-release combination product candidate of benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. KemPharm is also advancing KP201/IR, an acetaminophen-free immediate-release formulation of the Company's benzhydrocodone prodrug candidate. Both APADAZ and KP201/IR are intended for the treatment of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com or connect with us on Twitter, LinkedIn, Facebook and YouTube.

APADAZ

APADAZ was developed from KemPharm's proprietary LAT platform technology and is intended 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. KemPharm believes APADAZ is unique among prescription opioids in that it contains a prodrug that is chemically inert, or inactive, on its own. When ingested, enzymes in the gastrointestinal tract cleave the ligand from the prodrug (benzhydrocodone) and release the parent drug (hydrocodone), which can then exert its therapeutic effect. The final approved product labeling for APADAZ includes these and other data points but concludes that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

The approval of APADAZ via the 505(b)(2) pathway was based in part on pharmacokinetic studies with Vicoprofen®, Ultracet®, and Norco® in which APADAZ demonstrated exposure to hydrocodone and acetaminophen (APAP) that is expected to result in therapeutic effects equivalent to currently approved immediate-release hydrocodone/APAP combination products when administered orally as intended.

Indication:
APADAZ contains an opioid agonist and acetaminophen and is indicated 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.

Limitations of Use:
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve APADAZ for use in patients for whom alternative treatment options [e.g., non-opioid analgesics] have not been or are not expected tolerated, or have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Important Safety Information:

APADAZ is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity to hydrocodone or acetaminophen.

APADAZ contains benzhydrocodone, a Schedule II controlled substance. APADAZ can be abused and is subject to misuse, addiction, and criminal diversion.

Potential risks associated with APADAZ include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 CYP3A4 inhibitors and inducers, acetaminophen hepatoxicity risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants, risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, serious skin reactions, risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness, hypersensitivity/anaphylaxis, risks of use in patients with gastrointestinal conditions, risk of use in patients with seizure disorders, and withdrawal, risks of driving and operating machinery.

Potential drug interactions with APADAZ include:

- Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue APADAZ if serotonin syndrome is suspected.
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with APADAZ because they may reduce analgesic effect of APADAZ or precipitate withdrawal symptoms.
- Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydrocodone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.

Most common adverse reactions (>5%) are nausea, somnolence, vomiting, constipation, pruritus, dizziness, and headache.

The Full Prescribing Information for APADAZ contains the following Boxed Warning:

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; HEPATOTOXICITY; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse:

APADAZ exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient’s risk prior to prescribing APADAZ and monitor all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression:

Serious, life-threatening, or fatal respiratory depression may occur with use of APADAZ. Monitor for respiratory depression, especially during initiation of APADAZ or following a dose increase.

Accidental Ingestion:

Accidental ingestion of even one dose of APADAZ, especially by children, can result in a fatal overdose of hydrocodone.

Neonatal Opioid Withdrawal Syndrome:

Prolonged use of APADAZ during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction:

The concomitant use of APADAZ with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving APADAZ and any CYP3A4 inhibitor or inducer.

Hepatotoxicity:

APADAZ contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants:

Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of APADAZ and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

For Important Safety Information including full prescribing information, visit: www.kempharm.com

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, 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 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, 2017, 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.

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KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	10,488	4,650	22,125	8,764
General and administrative	3,420	3,574	6,552	6,840
Total operating expenses	13,908	8,224	28,677	15,604
Loss from operations	(13,908)	(8,224)	(28,677)	(15,604)
Other (expense) income:				
Interest expense related to amortization of debt issuance costs and discount	(390)	(390)	(780)	(780)
Interest expense on principal	(1,419)	(1,443)	(2,861)	(2,884)
Fair value adjustment related to derivative and warrant liability	5,562	3,523	(4,179)	(3,693)
Interest and other income, net	123	13	238	114
Total other (expense) income	3,876	1,703	(7,582)	(7,243)
Loss before income taxes	(10,032)	(6,521)	(36,259)	(22,847)
Income tax benefit	39	4	47	8
Net loss	$ (9,993)	$ (6,517)	$ (36,212)	$ (22,839)
Net loss per share:				
Basic	$ (0.65)	$ (0.44)	$ (2.41)	$ (1.56)
Diluted	$ (0.91)	$ (0.44)	$ (2.41)	$ (1.56)
Weighted average number of shares of common stock outstanding:				
Basic	15,317,536	14,649,586	15,056,161	14,648,291
Diluted	16,548,751	14,649,586	15,056,161	14,648,291

KEMPHARM, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and par value amounts)

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,497	$ 10,871
Restricted cash	1,100	1,100
Marketable securities	11,702	31,358
Trade date receivables	—	2,005
Prepaid expenses and other current assets	1,610	1,662
Total current assets	30,909	46,996
Property and equipment, net	1,841	2,004
Long-term investments	—	3,250
Other long-term assets	1,250	206
Total assets	$ 34,000	$ 52,456
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,967	$ 7,875
Current portion of convertible notes	3,333	3,333
Current portion of capital lease obligation	190	189
Other current liabilities	113	112
Total current liabilities	17,603	11,509
Convertible notes, less current portion, net	86,845	89,398
Derivative and warrant liability	11,888	7,709
Capital lease obligation, less current portion	466	562
Other long-term liabilities	743	794
Total liabilities	117,545	109,972
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 15,905,146 shares issued and outstanding as of June 30, 2018 (unaudited); 14,657,430 shares issued and outstanding as of December 31, 2017	2	1
Additional paid-in capital	117,391	107,209
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2018 (unaudited) and December 31, 2017	—	—
Accumulated deficit	(200,938)	(164,726)
Total stockholders' deficit	(83,545)	(57,516)
Total liabilities and stockholders' deficit	$ 34,000	$ 52,456

Exhibit 99.2

Q2 2018 Results

August 9, 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 May 11, 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.

Q2 2018 Results Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **R. LaDuane Clifton, CPA** – Chief Financial Officer, Secretary & Treasurer
- **Dan Cohen, M.A.L.S.** – EVP, Government & Public Relations

KemPharm Product Pipeline

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	Clinical	Oral and IN HAP Data	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

Recent Clinical Development Highlights

- On July 9th, announced top line results from the KP415.E01 efficacy and safety trial in children with ADHD

- On May 10th, announced topline results from the KP415.A03 Intravenous Human Abuse Potential trial of the KP415 prodrug

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
- No generic equivalent product
- Composition-based patent expires in 2032; pending applications, if granted, may potentially expire in 2037; potentially NCE eligible

KP415.E01 Efficacy Trial Overview

- First patient treatment occurred 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 Efficacy Trial Met it's 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						
	LS Mean (SE)		Difference in LS mean (SE)	95% Confidence Interval		
Statistical Measure	KP415	Placebo	KP415 – Placebo	KP415 – Placebo		p-Value
Mean difference in change from baseline across all post-dose time-points	-4.87 (0.62)	0.54 (0.70)	-5.41 (0.87)	-7.10	-3.71	<0.001

Differences in SKAMP-C Change Between KP415 and Placebo Were Statistically Significant

	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)	
Time	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.

Differences in PERMP-A Change Between KP415 and Placebo Were Statistically Significant

	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)	
Time	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.

Differences in PERMP-C Change Between KP415 and Placebo Were Statistically Significant

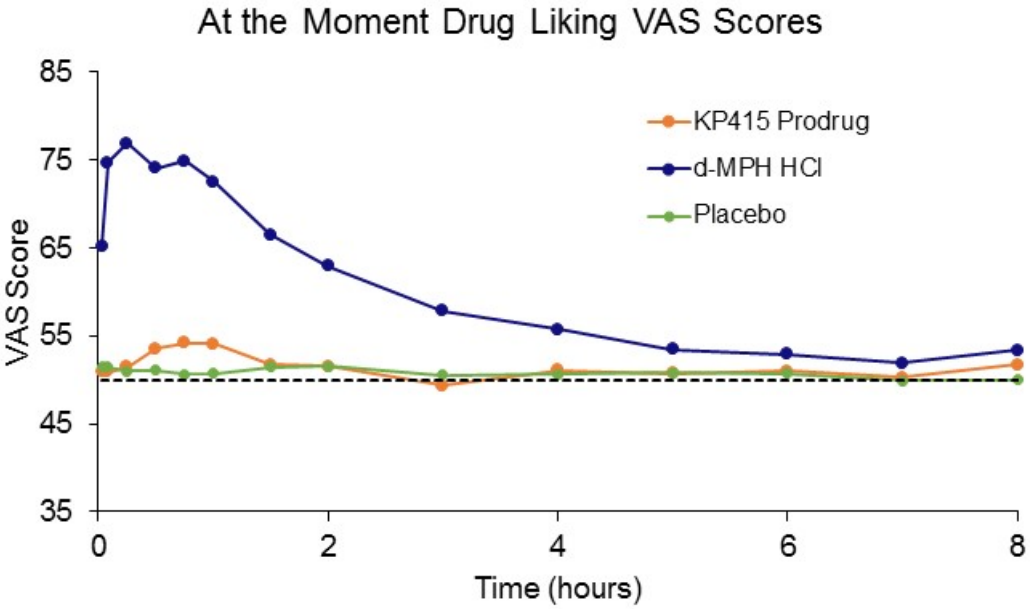
	PERMP-C Change at Visit 6 from Baseline			
	Baseline = predose Visit 5 (prespecified)*		Baseline = predose Visit 6 (post hoc)*	
	Difference in LS mean (SE)		Difference in LS mean (SE)	
Time	KP415 – Placebo	p-Value	KP415 – Placebo	p-Value
Predose	-0.97 (5.12)	0.850	0.07 (4.27)	0.986
0.5 hours postdose	20.06 (5.12)	<0.001	22.40 (4.27)	<0.001
1 hours postdose	29.24 (5.12)	<0.001	31.31 (4.27)	<0.001
2 hours postdose	40.60 (5.12)	<0.001	44.05 (4.27)	<0.001
4 hours postdose	33.64 (5.12)	<0.001	36.87 (4.27)	<0.001
8 hours postdose	23.57 (5.12)	<0.001	26.85 (4.27)	<0.001
10 hours postdose	18.38 (5.12)	<0.001	21.27 (4.27)	<0.001
12 hours postdose	12.55 (5.12)	0.014	15.33 (4.27)	<0.001
13 hours postdose	18.34 (5.12)	<0.001	21.36 (4.27)	<0.001

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

KP415.E01 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
- Additional secondary endpoints are also supportive of efficacy, including:
  - ADHD-RS-5
  - WREMB-R
  - 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®
- Based on the entirety of the KP415.E01 trial data, we believe KP415 has a differentiated efficacy profile with an early onset and long duration of therapeutic effect for the treatment of ADHD

Drug Liking VAS After IV Injection of KP415 Prodrug was Similar to Placebo



Note: d-MPH HCl = dexmethylphenidate hydrochloride
Drug Liking was assessed on a bipolar scale
(0 = Strong Disliking, 50 = Neutral, 100 = Strong Liking)
Subjects received equimolar doses of KP415 Prodrug and d-MPH HCl

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 continue based on:
  - Significant, near-term ADHD prodrug commercial opportunity
  - Differentiated onset and duration efficacy profile
  - Differentiated IV HAP data for serdexmethylphenidate, with oral and IN HAP data still to come
  - Long patent life and potential NCE status

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[1] 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 Expected Milestones

Product	Event	Date	
KP484	IND Filing	2017	✓
KP415	Initiate Pivotal Efficacy Study	2017	✓
Apadaz®	FDA Approval	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	2H 2018	
KP415	NDA Submission	Q1 2019	
KP484	Pivotal Efficacy Study Results	2019	
KP484	NDA Submission	2019	

KemPharm

Q2 2018 Results

August 9, 2018