# 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 8, 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**

**2500 Crosspark Road, Suite E126, Coralville, IA 52241**
**(319) 665-2575**
**(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 November 8, 2018, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended September 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 Third Quarter 2018 Results” dated November 8, 2018. |
| 99.2 | Presentation titled "Q3 2018 Results" dated November 8, 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: November 8, 2018

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

**EXHIBIT 99.1**

# KemPharm, Inc. Reports Third Quarter 2018 Results

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

**Development Highlights:**

- Announced positive topline results from KP415.E01 efficacy and safety trial in children with attention deficit hyperactivity disorder (ADHD)
- Announced positive topline results from the oral and intranasal human abuse potential (HAP) trials of KP415 Prodrug; successfully completed KP415 HAP clinical program
- Presented data from the intranasal and intravenous HAP trials of KP415 Prodrug at the American Academy of Child & Adolescent Psychiatry meeting

**Corporate Highlights:**

- Entered into a collaboration and license agreement with KVK Tech, Inc. for the commercialization of APADAZ® in the U.S.
- Announced technology collaboration with twoXAR, Inc. to develop prodrug-based therapies for multiple indications
- Hosted KOL investor event focused on the ADHD treatment landscape

**Financial Highlights:**

- Net loss of $0.94 per basic and diluted share for the quarter ended September 30, 2018, compared to net loss of $0.68 per basic and diluted share for the quarter ended September 30, 2017
- Completed an underwritten public offering of 8,333,334 shares of common stock at $3.00 per share and net proceeds of approximately $23.2 million
- Total cash and investments were $14.1 million at September 30, 2018, total cash and investments pro forma post-offering were approximately $37.3 million

**Celebration, FL – November 8, 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 third quarter ended September 30, 2018, including an update on clinical development events related to its prodrug development pipeline.

“This has been one of the most important periods in KemPharm’s history,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “In the span of just four months, we completed the KP415 efficacy and human abuse potential (HAP) programs, announced a definitive collaboration and license agreement with KVK for the U.S. commercial rights for APADAZ, entered into a technology collaboration with twoXAR to develop novel prodrugs, and solidified our balance sheet. As a result of these efforts, we believe we are now well-positioned to file a New Drug Application (NDA) as soon as the first quarter of 2019 for what we believe is a differentiated methylphenidate product for the high-demand ADHD treatment market, commercialize APADAZ with KVK, and create new opportunities to apply our prodrug expertise to under-served therapeutic areas.”

“Much has been accomplished recently; however, we have only just begun to unlock KemPharm’s value potential,” Mickle continued. “With partnering discussions for KP415 and KP484 advancing towards a potential year-end event, and launch preparation for APADAZ soon to commence in anticipation of a commercial launch in the second half of 2019, we believe the remainder of 2018 and all of 2019 will be a time of substantial growth and opportunity for our company.”

**Q3 2018 Financial Results:**

For Q3 2018, KemPharm’s reported net loss was $15.1 million, or $0.94 per basic and diluted share, compared to a net loss of $10.0 million, or $0.68 per basic and diluted share for the same period in 2017. Net loss for Q3 2018 was driven primarily by a 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 from $9.6 million in Q3 2017 to $18.0 million in Q3 2018, which was 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, which is comprised of cash, cash equivalents, restricted cash and marketable securities, was $14.1 million, which was a decrease of $15.2 million compared to June 30, 2018.

On October 10, 2018, the Company closed an underwritten public offering of 8,333,334 shares of its common stock at $3.00 per share, receiving net proceeds of approximately $23.2 million. Pro forma total cash and investments following the offering were approximately $37.3 million.

**Conference Call Information:**

KemPharm will host a conference call and live audio webcast with slide presentation on Thursday, November 8, 2018, at 4:30 p.m. ET, to discuss its corporate and financial results for the third 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: 8398090

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, November 8, 2018, at approximately 5:30 p.m., ET.

**Recent and Q3 2018 Activities:**

- **Entered Into License Agreement with KVK Tech for the Commercialization of APADAZ**

  On October 30, 2018, KemPharm announced that it had entered into a definitive collaboration and license agreement with KVK Tech, Inc. for the U.S. commercial rights to its FDA-approved prodrug product, APADAZ (benzhydrocodone and acetaminophen tablets). Under the terms of the agreement, KemPharm is eligible to receive up to an estimated $3.4 million in pre-launch payments and certain cost reimbursements, including a $2.0 million payment upon achievement of a specified milestone related to the initial formulary adoption of APADAZ, as well as an aggregate of up to $53 million in milestone payments tied to specific net sales levels. In addition, net profits will be shared between KemPharm and KVK up to 50% based on achieving specified net sales levels. KVK has the exclusive right for all commercial, manufacturing, packaging and distribution activities for APADAZ in the U.S. and will be responsible for all regulatory and commercialization-related expenses.

- **Announced Technology Collaboration with twoXAR, Inc. to Develop Prodrug-Based Therapies for Multiple Indications**

  On October 23, 2018, KemPharm and twoXAR, Inc. announced that they have entered into a technology collaboration to develop prodrug-based therapies for multiple therapeutic areas and indications. This collaboration combines twoXAR's AI-based technology to identify and de-risk drug product candidates developed with KemPharm's LAT™ technology to create new prodrugs that are designed to address unmet patient needs, improve the profile of drug product candidates and generate long-lived composition-of-matter patents.

- **Hosted KOL Investor Event Focused on the ADHD Treatment Landscape**

  On October 11, 2018, KemPharm hosted an investor event featuring a discussion with key opinion leaders and prescribing physicians in the field of ADHD. The KemPharm ADHD Investor Event was organized to provide investors with a comprehensive review of the dynamics influencing the ADHD treatment landscape, including current challenges and unmet medical needs, as well as an overview of KemPharm's ADHD prodrug portfolio, which is highlighted by its two lead investigational prodrug candidates for treating ADHD, KP415 and KP484.

- **Completed Underwritten Public Offering of Common Stock**

  On October 5, 2018, KemPharm announced the pricing of its underwritten public offering of 8,333,334 shares of its common stock at a price to the public of $3.00 per share. The transaction subsequently closed on October 10, 2018, and the Company received net proceeds of approximately $23.2 million. KemPharm intends to use the net proceeds of the offering primarily to fund an NDA submission for KP415, to initiate a pivotal trial for KP484 and for general corporate purposes.

- **Announced Positive Topline Results from Intranasal Human Abuse Potential Trial of KP415 Prodrug**

  On September 17, 2018, KemPharm announced topline results from its intranasal (IN) human abuse potential (HAP) clinical trial of serdexmethylphenidate (SDX, a prodrug of d-methylphenidate, or KP415 Prodrug), the major active pharmaceutical ingredient (API) in KP415 and KP484, KemPharm's investigational product candidates for the treatment of ADHD. In the IN HAP trial (KP415.A02), SDX produced significantly lower scores on the primary endpoint, maximal Drug Liking ($E_{max}$), and other abuse-related endpoints, compared to intranasal d-methylphenidate hydrochloride, indicating that SDX is not efficiently converted to active d-methylphenidate when snorted.

- **Announced Positive Topline Results from Oral Human Abuse Potential Trial of KP415 Prodrug**

  On September 11, 2018, KemPharm announced positive topline results from its oral HAP clinical trial of SDX. Results from the oral HAP trial (KP415.A01) indicate that the prodrug component of KP415 may have lower abuse potential compared to Focalin® XR (d-methylphenidate extended release capsules), a schedule II controlled substance, even when SDX is administered at oral doses up to 1.5 times higher than Focalin® XR on a molar basis. KemPharm will be presenting the data from all three HAP trials (intranasal, oral and intravenous), as well as the tampering study results, to the U.S. Food and Drug Administration as part of its human abuse potential assessment for SDX in the KP415 NDA.

- **Announced Positive Topline 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, its investigational ADHD product candidate that contains SDX and d-methylphenidate. Results from the trial (KP415.E01) indicated that KP415 successfully met the primary efficacy endpoint in patients with ADHD between the ages of 6 and 12 years. Analysis of a number of secondary endpoints, suggests an onset of action at 30 minutes with efficacy lasting up to 13 hours post-dose.

**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) technology. KemPharm utilizes its proprietary LAT 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 product pipeline is focused on the high need areas of ADHD, pain and other central nervous system disorders, and its co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of d-methylphenidate, but with differing extended-release/effect profiles, are intended for the treatment of ADHD. In addition, KemPharm has received FDA approval for APADAZ®, 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 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, 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Revenue | $ — | $ — | $ — | $ — |
| Operating expenses: | | | | |
| Research and development | 13,330 | 6,293 | 35,455 | 15,057 |
| General and administrative | 2,992 | 3,319 | 9,544 | 10,159 |
| Severance expense | 1,636 | — | 1,636 | — |
| Total operating expenses | 17,958 | 9,612 | 46,635 | 25,216 |
| Loss from operations | (17,958) | (9,612) | (46,635) | (25,216) |
| Other (expense) income: | | | | |
| Interest expense related to amortization of debt issuance costs and discount | (326) | (391) | (1,106) | (1,171) |
| Interest expense on principal | (1,367) | (1,448) | (4,228) | (4,332) |
| Fair value adjustment related to derivative and warrant liability | 4,468 | 1,312 | 289 | (2,381) |
| Interest and other income, net | 52 | 154 | 290 | 268 |
| Total other (expense) income | 2,827 | (373) | (4,755) | (7,616) |
| Loss before income taxes | (15,131) | (9,985) | (51,390) | (32,832) |
| Income tax benefit | 60 | 4 | 107 | 12 |
| Net loss | $ (15,071) | $ (9,981) | $ (51,283) | $ (32,820) |
| | | | | |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.94) | $ (0.68) | $ (3.33) | $ (2.24) |
| | | | | |
| Weighted average number of shares of common stock outstanding: | | | | |
| Basic and diluted | 16,033,923 | 14,657,430 | 15,385,663 | 14,651,371 |

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

| | September 30, 2018 (unaudited) | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,788 | $ 10,871 |
| Restricted cash | 1,100 | 1,100 |
| Marketable securities | 11,239 | 31,358 |
| Trade date receivables | — | 2,005 |
| Prepaid expenses and other current assets | 2,610 | 1,662 |
| Total current assets | 16,737 | 46,996 |
| Property and equipment, net | 1,817 | 2,004 |
| Long-term investments | — | 3,250 |
| Other long-term assets | 183 | 206 |
| Total assets | $ 18,737 | $ 52,456 |
| | | |
| **Liabilities and stockholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 14,677 | $ 7,875 |
| Current portion of convertible notes | 3,333 | 3,333 |
| Current portion of capital lease obligation | 210 | 189 |
| Other current liabilities | 103 | 112 |
| Total current liabilities | 18,323 | 11,509 |
| Convertible notes, less current portion, net | 87,171 | 89,398 |
| Derivative and warrant liability | 7,420 | 7,709 |
| Capital lease obligation, less current portion | 451 | 562 |
| Other long-term liabilities | 717 | 794 |
| Total liabilities | 114,082 | 109,972 |
| | | |
| Stockholders' deficit: | | |
| Common stock, $0.0001 par value, 250,000,000 shares authorized, 16,042,018 shares issued and outstanding as of September 30, 2018 (unaudited); 14,657,430 shares issued and outstanding as of December 31, 2017 | 2 | 1 |
| Additional paid-in capital | 120,662 | 107,209 |
| Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2018 (unaudited) and December 31, 2017 | — | — |
| Accumulated deficit | (216,009) | (164,726) |
| Total stockholders' deficit | (95,345) | (57,516) |
| Total liabilities and stockholders' deficit | $ 18,737 | $ 52,456 |


KemPharm
Q3 2018 Results
November 8, 2018

# Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, our planned clinical trials for our prodrug product candidates, the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) pathway and expedited FDA review, the clinical utility of our product candidates and our intellectual property position. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Quarterly Report on Form 10-Q filed with the SEC on August 10, 2018, and our other Periodic and Current Reports filed with the SEC. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Further, the information contained in this presentation speaks only as the date hereof. While we may elect to update the information in this presentation in the future, we disclaim any obligation to do so except to the extent required by applicable law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

## Q3 2018 Results Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **R. LaDuane Clifton, CPA** – Chief Financial Officer, Secretary & Treasurer
- **Gordon K. "Rusty" Johnson** – Chief Business Officer

# 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 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**

# Q3 2018 and Recent Highlights

## Corporate and Financial

- Entered into license agreement with KVK for the commercialization of APADAZ®
- Announced technology collaboration with twoXAR to develop prodrug-based therapies for multiple disease indications
- Hosted KOL investor event focused on the ADHD treatment landscape
- Completed public offering of 8,333,334 shares of common stock at $3.00 per share and net proceeds of approx. $23.2 million

## Q3 2018 and Recent Highlights

### Development

- Announced completion and positive topline results from the KP415.E01 Efficacy and Safety Trial in children with Attention Deficit/Hyperactivity Disorder (ADHD)

- Announced positive topline results from the oral and intranasal human abuse potential (HAP) trials of the KP415 Prodrug, or SDX (serdexmethylphenidate), and the completion of the SDX HAP clinical program with positive results from all three trials completed (intravenous, oral and intranasal)

- Presented data from the intranasal and intravenous HAP Trials of SDX at the American Academy of Child & Adolescent Psychiatry meeting

## APADAZ® Commercial License Agreement with KVK

- KVK is a private company founded in 2004 and is one of the largest controlled substance manufacturers and distributors in the U.S.
- 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
- 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

## KemPharm Prodrug Technology Collaboration with twoXAR

- Technology collaboration 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
- 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)

## KemPharm ADHD KOL Investor Event Highlights

- Ann Childress, MD - *"ADHD Treatment Landscape and Using the Laboratory Classroom to Determine Drug Effects"*
  - Presented a review of the ADHD patient and treatment landscape, including key benefits and drawbacks of current ADHD medications and potential opportunities for improvement with examples from the KP415.E01 efficacy study

- Matthew Brams, MD - *"Prescribing ADHD Medications in a Large Outpatient Practice: The Good, The Bad, and the Ugly"*
  - Focused on key unmet needs (faster onset, longer duration, improved tolerability and once-daily dosing) that he believes must be addressed by next-generation ADHD products

- Timothy E. Wilens, MD - *"Nonmedical Use of Prescription Stimulants"*
  - Discussed the prevalence of stimulant misuse and the need for next-generation ADHD medications that reduce abuse potential

## 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
- 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

## Follow-on Financing Update

- Completed an underwritten public offering of 8.3 million shares on October 10, 2018, receiving net proceeds of approx. $23.2 million
- Offering was strategically timed to improve our balance sheet which we believe may strengthen our negotiating position with potential KP415 and KP484 strategic partners
- Common shares outstanding on September 30, 2018, were 16.0 million; pro forma common shares outstanding post-offering were 24.4 million
- Total cash and investments[1] were $14.1 million as of September 30, 2018, pro forma cash post-offering was approx. $37.3 million

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

# 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

# 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