

**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): March 29, 2018

KemPharm, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer Identification No.)

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 March 29, 2018, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter and year ended December 31, 2017, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release titled "KemPharm Reports Fourth Quarter and Year End 2017 Results" dated March 29, 2018.</u>
99.2	<u>Presentation titled "Q4 and FY 2017 Results" dated March 29, 2018.</u>

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: March 29, 2018

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer



KemPharm Reports Fourth Quarter and Year End 2017 Results

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

Development & Regulatory Highlights:

- FDA Approval Announced of APADAZ™ (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain on February 23, 2018
- Initiated Pivotal Efficacy Trial of KP415 for the Treatment of Attention Deficit, Hyperactivity Disorder (ADHD)
- Announced Positive Topline Results from KP415 Pharmacokinetic Study in Children and Adolescents With ADHD
- Announced FDA Acceptance of KP484 IND; Efficacy Studies Expected to Initiate in 2018
- Received USAN Approval for “Asalhydromorphone” as Nonproprietary Name for Novel Prodrug Candidate, KP511
- Patent Granted for KP606, KP511-related family on January 23, 2018
- Entered into Licensing and Assignment Agreement with Genco Sciences to Develop a Prodrug-Based Therapy for Potential Rare Pediatric Indications of Tourette’s Syndrome with ADHD

Corporate & Financial Highlights:

- Net loss of \$0.72 per basic and diluted share for the quarter ended December 31, 2017; net loss of \$2.96 per basic and diluted share for the year ended December 31, 2017
- Total cash and security-related amounts were \$48.6 million at December 31, 2017
- Initiated sale of common stock during Q1 2018 under the ATM offering, raising \$2.9M in gross proceeds from the sale of 446,111 shares of common stock

Coralville, IA – March 29, 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 fourth quarter and full year ended December 31, 2017, including an update on development and regulatory events involving its prodrug development pipeline.

“The past several months has been an important period for KemPharm, highlighted by the initiation of a pivotal efficacy trial of our lead ADHD prodrug product candidate KP415 and the FDA approval of APADAZ, our benzhydrocodone/acetaminophen prodrug product for short-term management of acute pain,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “These notable events, coupled with several advancements across our product pipeline, are a testament to the value potential of our LAT™ (Ligand Activated Therapy) prodrug platform and the team. We believe that these events have set the stage for what could be a milestone-rich 2018 and beyond.”

“Since inception, KemPharm’s vision has been to develop a portfolio of proprietary prodrugs that are designed to be differentiated versions of widely prescribed, currently approved drugs, and that can successfully complete the rigorous FDA regulatory pharmaceutical approval process,” Dr. Mickle added. “We believe the approval of APADAZ has validated the vision we have for our platform products, and our co-lead clinical development product candidates, KP415 and KP484, are progressing as planned.”

“We believe we are at a key inflection point in the company’s growth and look forward to pursuing multiple internal and external opportunities to maximize our prodrug expertise and the potential that prodrugs can offer throughout the healthcare continuum,” Mickle concluded.

Q4 and Full-Year 2017 Financial Results:

For the quarter ended December 31, 2017, KemPharm's reported net loss was \$10.6 million, or \$0.72 per basic and diluted share, compared to net loss of \$9.9 million, or \$0.68 per basic and diluted share, for the same period in 2016. Net loss for Q4 2017 was driven primarily by a loss from operations of \$8.2 million, net interest expense and other items of \$1.7 million, and non-cash fair value adjustment expense of \$0.7 million. Loss from operations decreased \$2.6 million from \$10.8 million in Q4 2016 to \$8.2 million in Q4 2017, which was primarily due to a decrease of \$2.4 million in research and development expenses, and a decrease of \$0.2 million in general and administrative expenses.

Net loss for the year ended December 31, 2017, was \$43.4 million, or \$2.96 per basic and diluted share, an increase of \$26.9 million compared to net loss for the year ended December 31, 2016 of \$16.5 million, or \$1.13 per basic and diluted share. The increase in net loss was primarily attributable to a period-over-period change of \$35.6 million in fair value adjustment related to changes in the derivative and warrant liability for each period resulting in non-cash expense of \$3.1 million for the year ended December 31, 2017, compared to non-cash income of \$32.5 million for the year ended December 31, 2016. The increase in net loss was partially offset by a decrease of \$4.1 million in loss from operations, which was \$33.4 million for the year ended December 31, 2017, as compared to \$37.5 million for the year ended December 31, 2016. The decrease in loss from operations was driven primarily by the non-recurrence in 2017 of severance expense and a reduction of \$1.2 million in general and administrative expenses. In addition, non-cash loss on extinguishment of debt recognized during the year ended December 31, 2016, did not recur in 2017.

As of December 31, 2017, total cash and security-related amounts, which is comprised of cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments, was \$48.6 million, which reflected a decrease of \$7.0 million compared to September 30, 2017.

During Q1 2018, the Company initiated sales of its common stock under its ATM ("at-the-market") offering, and through March 28, 2018, has raised gross proceeds of \$2.9 million from the sale of 446,111 common shares, with remaining availability under the ATM offering of \$47.1 million.

Based on the Company's current operating forecast, existing resources as of December 31, 2017 are not expected to be sufficient to fund operating expenses and capital expenditure requirements through Q1 2019, primarily due to entering into certain materials supply arrangements subsequent to the approval of APADAZ required to prepare for product commercialization, as well as an acceleration of certain elements of the KP415 clinical program. As a result, the Company anticipates that the audited financial statements included with its Annual Report on Form 10-K for the year ended December 31, 2017, to be filed with the Securities and Exchange Commission, will contain an audit opinion from its independent registered public accounting firm that will include a going concern emphasis matter paragraph. The Company plans to continue its ATM offering to provide a portion of the capital needed to fund ongoing operations.

Conference Call Information:

The Company will host a conference call and live audio webcast with slide presentation on Thursday, March 29, 2018, at 4:30 p.m. ET, to discuss its corporate and financial results for the third quarter 2017. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 7772039

The live webcast with accompanying slides 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 at approximately 5:30 p.m., ET on March 29, 2018.

Recent and Fourth Quarter 2017 Activities:

- **Announced FDA Approval of APADAZ (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain**

On February 23, 2018, KemPharm announced that the FDA approved its New Drug Application (NDA) for APADAZ 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. APADAZ is an immediate release (IR) combination of KemPharm's prodrug, benzhydrocodone, and acetaminophen (APAP).

- **Initiated Pivotal Efficacy Trial of KP415, an ADHD Prodrug Composition Candidate**

On January 8, 2018, KemPharm reported the successful December initiation of a "classroom-style" pivotal efficacy trial of KP415, the company's extended release d-methylphenidate (d-MPH) prodrug composition product candidate for the treatment of ADHD. The trial is designed to support a potential label for KP415 for both early onset and long duration of treatment effect in ADHD patients. The trial is a multicenter, dose-optimized, double-blind, randomized, placebo-controlled, parallel efficacy laboratory classroom trial with children aged 6 to 12 years with a diagnosis of ADHD. Enrollment in the trial is expected to total approximately 140 patients across five clinical sites in the United States, and it is anticipated that all patients will have completed the trial by the end of second quarter of 2018. Each patient that completes the trial will be treated for a total of up to four weeks.

Previously, on November 16, 2017, KemPharm reported the completion of an End-of-Phase 2 (EOP2) meeting with the FDA for KP415. KemPharm held the EOP2 meeting with the FDA to discuss the status of the proposed clinical, non-clinical and abuse liability studies, as well as chemistry, manufacturing, and controls (CMC) programs required for eventual submission of an NDA for KP415.

- **Announced that the FDA Granted Clearance for the KP484 IND, Enabling KP484 to Proceed to Clinical Studies**

On November 2, 2017, KemPharm announced that the FDA completed its safety review of the Investigational New Drug (IND) application for KP484, the Company's prodrug product candidate of "super-extended" release d-MPH and concluded that the company may proceed with its planned clinical investigation for the treatment of ADHD. Submitted under Section 505(i) of the Federal Food, Drug, and Cosmetic Act, KemPharm's IND proposes to develop KP484 along a similar clinical trial pathway as its current co-lead investigation prodrug of d-MPH for the treatment of ADHD, KP415. Efficacy studies of KP484 are anticipated to be initiated in 2018.

- **Received USAN Approval for “Asalhydromorphone” as Nonproprietary Name for Novel Prodrug Candidate, KP511**

On November 6, 2017, KemPharm announced that the USAN Council approved the use of the nonproprietary name, "Asalhydromorphone (Asal-HM)," for use as the descriptor for the active pharmaceutical ingredient of its opioid-base pain treatment product candidate, KP511. Asal-HM is a prodrug of hydromorphone being developed as a potentially less abusable hydromorphone product for the treatment of pain severe enough to require daily, long-term opioid treatment. Chemically, Asal-HM (KP511) is a conjugate of hydromorphone and two acetylsalicylic acid (aspirin) moieties. It is believed that the resulting conjugate may lead to a lower abuse potential than hydromorphone by itself.

- **Granted Patent for KP606, a Prodrug of Oxycodone; Additional Patent Granted for the KP511-related family, a Prodrug of Hydromorphone**

On January 23, 2018, KemPharm announced further enhancements to its U.S. and global intellectual property estate governing its portfolio of prodrug product candidates with the receipt of an initial patent issued for KP606, KemPharm’s prodrug of oxycodone (U.S. Patent No. 9,850,252), as well as an additional composition of matter patent to enhance the existing family of patents related to KP511 (U.S. Patent 9,849,185).

- **Entered into Licensing and Assignment 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 entered into a technology licensing and assignment agreement with Genco Sciences, LLC (Genco) whereby KemPharm anticipates utilizing Genco’s early research-stage proprietary program to devise a unique prodrug to be developed as a treatment for pediatric Tourette’s syndrome when accompanied by ADHD. Under terms of the agreement, KemPharm will be responsible for financing and managing all product development. In exchange, KemPharm will retain full intellectual property and commercial ownership of any product developed as a result of this agreement, and Genco will be eligible to receive certain milestone and royalty-based or value-share payments.

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, the company has received FDA approval for APADAZ™, an immediate-release combination product candidate of benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. The company 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.

APADAZ

APADAZ was developed from KemPharm's proprietary LAT (Ligand Activated Therapy) 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 hepatotoxicity 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, 2016, 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.

Investor Contacts:

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Executive VP, Government and Public Relations

KemPharm, Inc.

202-329-1825

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

	December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,871	\$ 16,762
Restricted cash	1,100	1,100
Marketable securities	31,358	51,003
Trade date receivables	2,005	5,003
Prepaid expenses and other current assets	1,662	489
Total current assets	46,996	74,357
Property and equipment, net	2,004	1,970
Long-term investments	3,250	8,200
Other long-term assets	206	360
Total assets	\$ 52,456	\$ 84,887
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,875	\$ 6,444
Current portion of convertible notes	3,333	—
Current portion of capital lease obligation	189	157
Other current liabilities	112	41
Total current liabilities	11,509	6,642
Convertible notes, less current portion, net	89,398	91,170
Derivative and warrant liability	7,709	4,618
Capital lease obligation, less current portion	562	657
Other long-term liabilities	794	496
Total liabilities	109,972	103,583
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,657,430 shares issued and outstanding as of December 31, 2017; 14,646,982 shares issued and outstanding as of December 31, 2016	1	1
Additional paid-in capital	107,209	102,643
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2017 or December 31, 2016	—	—
Accumulated deficit	(164,726)	(121,340)
Total stockholders' deficit	(57,516)	(18,696)
Total liabilities and stockholders' deficit	\$ 52,456	\$ 84,887

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

	Year ended December 31,		
	2017	2016	2015
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	20,593	20,472	13,931
General and administrative	12,773	14,000	8,883
Severance expense	—	3,010	—
Total operating expenses	33,366	37,482	22,814
Loss from operations	(33,366)	(37,482)	(22,814)
Other (expense) income:			
Loss on extinguishment of debt	—	(4,740)	—
Interest expense related to amortization of debt issuance costs and discount	(1,561)	(1,616)	(1,909)
Interest expense on principal	(5,776)	(5,511)	(2,671)
Fair value adjustment related to derivative and warrant liability	(3,091)	32,465	(27,276)
Interest and other income, net	365	353	32
Total other (expense) income	(10,063)	20,951	(31,824)
Loss before income taxes	(43,429)	(16,531)	(54,638)
Income tax benefit (expense)	43	15	(26)
Net loss	\$ (43,386)	\$ (16,516)	\$ (54,664)
Net loss per share:			
Basic and diluted	\$ (2.96)	\$ (1.13)	\$ (7.42)
Weighted average number of shares of common stock outstanding:			
Basic and diluted	14,652,898	14,597,053	7,368,681



KemPharm

Q4 and FY 2017 Results

March 29, 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 Annual Report on Form 10-K for the year ended December 31, 2016, and our other Periodic and Current Reports filed with the Securities and Exchange Commission. 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.



Q4 and FY 2017 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



Q4 and FY 2017 Financial Results

- Q4 2017 net loss of \$10.6M, or \$0.72 per basic and diluted share, vs. Q4 2016 net loss of \$9.9M, or \$0.68 per basic and diluted share
- Net loss for Q4 2017 was primarily due to loss from operations of \$8.2 million and net interest expense and other items of \$1.7 million; and by non-cash fair value adjustment expense of \$0.7 million related to the warrant derivative liability
- Loss from operations decreased to \$8.2M in Q4 2017, as compared to \$10.8M in Q4 2016, which was primarily driven by a decrease in research and development and general and administrative spending of \$2.4 million and \$0.2 million, respectively, period over period
- FY 2017 net loss of \$43.4M, or \$2.96 per basic and diluted share, vs. FY 2016 net loss of \$16.5M, or \$1.13 per basic and diluted share
- Net loss for FY 2017 was primarily due to loss from operations of \$33.4M, net interest expense and other items of \$6.9M and non-cash fair value adjustment expense of \$3.1M



Q4 and FY 2017 Financial Results

- Loss from operations decreased to \$33.4M in FY 2017, as compared to \$37.5M in FY 2016, primarily driven by the non-recurrence in 2017 of severance expense of \$3.0M and a reduction in G&A spending of \$1.2M
- Total cash of \$48.6M as of 12/31/2017, a decrease of \$7.0M vs. 9/30/2017 *(Includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments)*
- Initiated sales of common stock under the Company's ATM ("at-the-market") offering during Q1 2018, raising gross proceeds of \$2.9M on the sale of 446,111 shares, with remaining availability under the ATM offering of \$47.1 million
- Existing resources as of December 31, 2017 are not expected to be sufficient to fund operating expenses and capital expenditure requirements through Q1 2019, due to arrangements related to the approval of APADAZ for product commercialization, and an acceleration of certain elements of the KP415 clinical program



Recent Development and Regulatory Updates

- Announced FDA Approval of APADAZ™ for the Short-Term Management of Acute Pain
- Initiated Pivotal Efficacy Trial of KP415
- Announced Positive Topline Results from KP415 PK Study in Children and Adolescents with ADHD
- Announced FDA Acceptance of KP484 IND
- Received USAN Approval for “Asalhydromorphone” as Nonproprietary Name for KP511
- Entered into Licensing and Assignment Agreement with Genco Sciences to Develop a Prodrug-Based Therapy for Potential Rare Pediatric Indications of Tourette’s Syndrome with ADHD



ADHD Prodrug Product Pipeline – Addressing Unmet Needs

KP415 – ADHD Product Candidate for Fast Onset and Longer Total Duration

- Extended release product candidate
- Prodrug of d-MPH co-formulated with IR d-MPH
- Pivotal efficacy trial initiated; data expected by midyear 2018
- Recent, positive PK data suggests pivotal data could be applicable across pediatric, adolescent and adult populations
- Human abuse liability clinical data in 2018 – IV, oral and IN
- KP415 NDA filing expected as early as Q1 2019

KP484 – ADHD Product Candidate with Super Extended Release Properties

- Super-extended release product candidate
- Prodrug of d-MPH
- IND accepted; Efficacy studies expected to initiate in 2018
- Initial data suggest long-acting characteristics similar to Shire's MYDAYIS™ (amphetamine-based)
- Expect to benefit from KP415's development program
- Human abuse liability clinical data in 2018 – IV, oral and IN
- Potential NDA as early as 2019



KemPharm Near-Term Product Candidates

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	Clinical	PK + Efficacy Data	Q1 2019
	KP484	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2019
PAIN	Apadaz™	Hydrocodone/ APAP	FDA Approved	Commercial Partnerships	N/A
	KP201/IR	Hydrocodone	Clinical	IN HAL Data	2019 with Priority Review
	KP511/ER	Hydromorphone	Clinical	POC in ER Formulation	2019 with Priority Review
	KP511/IR	Hydromorphone	Clinical	HAL and BE Data	2019 with Priority Review



KemPharm Expected Timelines

Product	Event	Date	
KP484	IND Filing	2017	✓
KP415	Initiate Pivotal Efficacy Study	2017	✓
Apadaz™	FDA Approval	02/23/18	✓
KP415 / KP484	IV Human Abuse Liability (HAL) Data	2018	
KP415	Pivotal Efficacy Study Results	2018	
KP484	Initiate Pivotal Efficacy Study	2018	
KP415 / KP484	Oral and IN HAL Data	2018	
KP415	NDA Submission	2019	
KP484	Pivotal Efficacy Study Results	2019	
KP484	NDA Submission	2019	





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Q4 and FY 2017 Results

March 29, 2018