

**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): February 28, 2019**

**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.)

**1180 Celebration Boulevard, Suite 103, Celebration, FL**  
(Address of Principal Executive Offices)

**34747**  
(Zip Code)

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

(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 1.01 Entry into a Material Definitive Agreement.

On February 28, 2019, KemPharm, Inc., a Delaware corporation referred to herein as we, us, our, the Company or KemPharm, entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to \$15.0 million of shares of our common stock, or the Purchase Shares, from time to time over the 36-month term of the Purchase Agreement, and we shall issue an additional 120,200 shares of our common stock to Lincoln Park as commitment shares under the Purchase Agreement, or the Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, or the Registration Rights Agreement, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement.

After the Commencement Date (as defined below), on any business day over the term of the Purchase Agreement, we have the right, in our sole discretion, to present Lincoln Park with a purchase notice, each referred to herein as a Purchase Notice, directing Lincoln Park to purchase up to 100,000 Purchase Shares per business day, or a Regular Purchase, which amounts may be increased to up to 200,000 Purchase Shares depending on the market price of our common stock at the time of sale, in a purchase amount up to \$2,000,000 per purchase, provided that Lincoln Park will not be required to buy shares pursuant to a Purchase Notice that was received by Lincoln Park on any business day on which the last closing trade price of our common stock on the Nasdaq Global Market (or alternative national exchange in accordance with the Purchase Agreement) is below \$1.00 per share. The Purchase Agreement provides for a purchase price per Purchase Share, or the Purchase Price, equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; and
- the average of the three lowest closing sale prices for our common stock during the ten consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition, on any date on which we submit a Purchase Notice to Lincoln Park, we also have the right, in our sole discretion, to present Lincoln Park with an accelerated purchase notice, or an Accelerated Purchase Notice, directing Lincoln Park to purchase an amount of stock, or an Accelerated Purchase, equal to up to the less of (i) three times the number of shares purchased pursuant to such Regular Purchase; and (ii) 30% of the aggregate shares of our common stock traded during all or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed on the applicable Accelerated Purchase date, the portion of the normal trading hours on the applicable Accelerated Purchase date prior to such time that any one of such thresholds is crossed, with such period of time on the applicable Accelerated Purchase date, referred to herein as the Accelerated Purchase Measurement Period, provided that Lincoln Park will not be required to buy Purchase Shares pursuant to an Accelerated Purchase Notice that was received by Lincoln Park on any business day on which the last closing trade price of our common stock on the Nasdaq Global Market (or alternative national exchange in accordance with the Purchase Agreement) is below \$1.50 per share. The purchase price per share for each such Accelerated Purchase will be equal to the lesser of:

- 97% of the volume weighted average price of our common stock during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date; and
- the closing sale price of our common stock on the applicable Accelerated Purchase date.

We may also direct Lincoln Park on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Purchase Agreement, to purchase an amount of stock, or an Additional Accelerated Purchase, equal to up to the less of (i) three times the number of shares purchased pursuant to such Regular Purchase; and (ii) 30% of the aggregate shares of our common stock traded during a certain portion of the normal trading hours on the applicable Additional Accelerated Purchase date as determined in accordance with the Purchase Agreement, such period of time on the applicable Additional Accelerated Purchase date is referred to herein as the Additional Accelerated Purchase Measurement Period, provided that the closing price of our common stock on the business day immediately preceding such business day is not below \$1.50 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement). Additional Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price of our common stock during the applicable Additional Accelerated Purchase Measurement Period on the applicable Additional Accelerated Purchase date; and
  - the closing sale price of our common stock on the applicable Additional Accelerated Purchase date.
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The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the Purchase Price. The aggregate number of shares that we can sell to Lincoln Park under the Purchase Agreement may in no case exceed 5,288,425 shares of common stock (which is equal to approximately 19.99% of the common stock outstanding immediately prior to the execution of the Purchase Agreement, or the Exchange Cap, unless (i) stockholder approval is obtained to issue Purchase Shares above the Exchange Cap, in which case the Exchange Cap will no longer apply, or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$2.3064 per share (which represents the average of the closing price of our common stock on the Nasdaq Global Market for the five business days immediately preceding the signing of the Purchase Agreement, plus an incremental amount to account for the issuance of the Commitment Shares to Lincoln Park); provided that at no time shall Lincoln Park (together with its affiliates) beneficially own more than 9.99% of our common stock.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions. Sales under the Purchase Agreement may commence only after certain conditions have been satisfied, the date on which all requisite conditions have been satisfied is referred to herein as the Commencement Date, which conditions include the delivery to Lincoln Park of a prospectus supplement covering the Commitment Shares and the Purchase Shares, approval for listing on Nasdaq Global Market of the Purchase Shares and the Commitment Shares, the issuance of the Commitment Shares to Lincoln Park, and the receipt by Lincoln Park of a customary opinion of counsel and other certificates and closing documents. We anticipate that such conditions will be satisfied on or around March 1, 2019. The Purchase Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common stock. While we have agreed to reimburse Lincoln Park for a limited portion of the fees it incurred in connection with the Purchase Agreement, we did not pay any additional amounts to reimburse or otherwise compensate Lincoln Park in connection with the transaction. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings (other than restrictions on our ability to enter into variable rate transactions described in the Purchase Agreement), rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. We may deliver Purchase Notices under the Purchase Agreement, subject to market conditions, and in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement. Any proceeds that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

The issuance of the Purchase Shares and Commitment Shares will be registered pursuant to our effective shelf registration statement on Form S-3 (File No. 333-213926), or the Registration Statement, and the related base prospectus included in the Registration Statement, as supplemented by a prospectus supplement to be filed on or around the Commencement Date. A copy of the legal opinion as to the legality of the shares of common stock subject to the Purchase Agreement will be filed as Exhibit 5.1 to our Annual Report on form 10-K for the fiscal year ending December 31, 2018.

The foregoing is a summary description of certain terms of the Purchase Agreement and the Registration Rights Agreement and, by its nature, is incomplete. Copies of the Purchase Agreement and the Registration Rights Agreement will be filed as exhibits to our Annual Report on Form 10-K for the fiscal year ending December 31, 2018. The foregoing descriptions of the Purchase Agreement and the Registration Rights Agreement are qualified in its entirety by reference to such exhibits.

The Purchase Agreement and Registration Rights Agreement contain customary representations and warranties, covenants and indemnification provisions that the parties made to, and solely for the benefit of, each other in the context of all of the terms and conditions of such agreements and in the context of the specific relationship between the parties thereto. The provisions of the Purchase Agreement and Registration Rights Agreement, including any representations and warranties contained therein, are not for the benefit of any party other than the parties thereto and are not intended as documents for investors and the public to obtain factual information about the current state of affairs of the parties thereto. Rather, investors and the public should look to other disclosures contained in our annual, quarterly and current reports we may file with the Securities and Exchange Commission.

The information contained in this Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy the shares of our common stock discussed herein, nor shall there be any offer, solicitation, or sale of the shares in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

Additionally, on February 28, 2019, in connection with entering into the Purchase Agreement, we entered into an amendment, or the Amendment, with Deerfield Private Design Fund III, L.P., or Deerfield, to that certain Senior Secured Convertible Note, or the Deerfield Note, and Warrant, or the Deerfield Warrant, previously issued by us to Deerfield. The Amendment, among other things, clarified that the anti-dilution protections contained in the Deerfield Convertible Note and Deerfield Warrant would not apply to the offerings contemplated under the Purchase Agreement or that certain Common Stock Sales Agreement, dated as of September 4, 2018, by and between us and RBC Capital Markets, LLC. The Amendment also includes a waiver from Deerfield regarding any rights it may have under our amended and restated investor rights agreement in connection with the Registration Rights Agreement. Except as modified by the Amendment, all terms and conditions of the Deerfield Convertible Note and Deerfield Warrant remain in full force and effect. The foregoing description of the Amendment is not complete and is qualified in its entirety by reference to the full text of the Amendment, a copy of which will be filed as an exhibit to our to our Annual Report on Form 10-K for the fiscal year ending December 31, 2018.

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## Forward Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements about the offering under the Purchase Agreement, including when any applicable closing conditions under the Purchase Agreement may be satisfied, and other statements containing the words “expect,” “intend,” “may,” “will,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, uncertainties inherent in the initiation of future clinical trials and such other factors as are set forth in the risk factors detailed in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the U.S. Securities and Exchange Commission on November 9, 2018 under the heading “Risk Factors.” In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof.

## Item 2.02 Results of Operations and Financial Condition.

On February 28, 2019, we, issued a press release announcing our corporate and financial results for the quarter and year ended December 31, 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 our 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release titled “KemPharm Reports Q4 and FY 2018 Results” dated February 28, 2019.</a>
99.2	<a href="#">Presentation titled “Quarterly Update Call - Q4 and FY 2018” dated February 28, 2019.</a>

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**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: February 28, 2019

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer

## **KemPharm Reports Q4 and FY 2018 Results**

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

### **Development & Regulatory Highlights:**

- Completed KP415 clinical and human abuse potential programs
- Received approval of APADAZ<sup>®</sup>
- Enhanced pipeline with the addition of KP879, a potential new treatment for Stimulant Use Disorder

### **Corporate Highlights:**

- Entered into collaboration and license agreement with KVK-Tech, Inc. for the commercialization of APADAZ<sup>®</sup> in the U.S.
- Announced technology collaboration with twoXAR, Inc. to develop prodrug-based therapies for multiple indications

### **Financial Highlights:**

- Completed an underwritten public offering of approximately 8.3 million shares of common stock at \$3.00 per share, receiving net proceeds of approximately \$23.1 million
- Reduced debt by \$9.6 million via exchange into preferred shares
- Q4 2018 net loss of \$0.20 per basic share, and \$0.21 per diluted share
- FY 2018 net loss of \$3.15 per basic and diluted share
- Total cash and investments were \$22.4 million at December 31, 2018

**Celebration, FL – February 28, 2019** – 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 quarter and full-year ended December 31, 2018, including an update on the KP415/KP484 partnering process and APADAZ<sup>®</sup> launch preparations.

“2018 was a period of significant accomplishment and value creation for KemPharm,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “We began the year with KP415 just entering into an efficacy trial and the human abuse potential trials had yet to kick-off, as well as APADAZ<sup>®</sup> awaiting FDA review. By the close of 2018, KP415 was NDA-ready with efficacy and human abuse potential data unlike any methylphenidate product on the market today, and APADAZ was an approved product which had been successfully partnered with KVK Tech. In 2018, we also added a new product to our pipeline, KP879, targeting a treatment opportunity – Stimulant Use Disorder (SUD) – for which there is no FDA-approved medication. In addition, we entered into a technology collaboration with twoXAR to develop novel prodrugs, and solidified our balance sheet to carry our plan forward.”

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“With 2019 underway, our immediate focus is on KP415 and KP484. Due to the recent government shutdown, our pre-NDA meeting with the FDA has been delayed into the second quarter. However, once that meeting is complete, we expect to file the NDA for KP415 shortly thereafter and also in the second quarter,” continued Dr. Mickle. “With regard to the KP415/KP484 partnering process, we believe that we are in a strong position with late-stage discussions with a number of parties in a competitive process. We have been working to advance the potential partners that were most active in December, and have also added additional parties since that time. While there are no assurances, we feel confident that this is a robust, competitive process with the potential to provide KP415/KP484 the best opportunity to maximize value for KemPharm. We believe the added time and effort will be worth it.”

“Commercial activities for APADAZ continue to proceed according to plan, with KVK expecting to launch commercially in the second half of 2019,” concluded Dr. Mickle. “We continue to support KVK’s launch activities and payor outreach efforts. Two essential items to support a successful launch were completed earlier this year when we received FDA approval of two additional dosage strengths of APADAZ in January, and the recent addition of APADAZ to compendia with pricing similar to current generics.”

#### **Q4 and FY 2018 Financial Results:**

For the quarter ended December 31, 2018, KemPharm’s reported net loss was \$5.2 million, or \$0.20 per basic share and \$0.21 per diluted share, compared to a net loss of \$10.6 million, or \$0.72 per basic and diluted share for the same period in 2017. Net loss for Q4 2018 was driven primarily by an operating loss of \$9.3 million and net interest expense and other items of \$1.6 million, partially offset by non-cash fair value adjustment income of \$5.7 million. The operating loss of \$9.3 million for Q4 2018 was an increase of \$1.1 million compared to \$8.2 million in Q4 2017, which was primarily due to increases of \$0.8 million in research and development expenses and \$0.4 million in general and administrative expenses, respectively.

For the year ended December 31, 2018, net loss was \$56.5 million, or \$3.15 per basic and diluted share, compared to a net loss of \$43.4 million, or \$2.96 per basic and diluted share for the year ended December 31, 2017. FY 2018 net loss was driven primarily by operating loss of \$55.9 million and net interest expense and other items of \$6.5 million, partially offset by non-cash fair value adjustment income of \$6.0 million. Operating loss for FY 2018 of \$55.9 million was an increase of \$22.5 million compared to the FY 2017 operating loss of \$33.4 million, which was primarily due to an increase of \$21.2 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 December 31, 2018, total cash and investments, which is comprised of cash, cash equivalents, restricted cash and marketable securities, was \$22.4 million, which was an increase of \$8.3 million compared to September 30, 2018.

#### **Common Stock Purchase Agreement with Lincoln Park Capital:**

KemPharm today also announced that it has entered into a common stock purchase agreement and registration rights agreement (together, the Agreements), with Lincoln Park Capital Fund, LLC (LPC), a Chicago-based institutional and current KemPharm investor. Pursuant to the Agreements, the Company has the right to sell, at its sole discretion, to LPC up to \$15 million of common stock over a 36-month period. KemPharm will control the timing of any sales to LPC and LPC will be obligated to make purchases of KemPharm common stock upon receipt of requests from KemPharm in accordance with the Agreements. Proceeds will be used for general corporate purposes.

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There are no upper limits to the price per share LPC may pay to purchase up to the \$15 million of common stock subject to the Agreements, and the purchase price of the shares will be based on the then prevailing market prices of the Company's shares at the time of each sale to LPC as described in the Agreements. As consideration for LPC's commitment to purchase shares of common stock under the Agreements, upon filing of the related prospectus supplement, KemPharm will issue 120,200 shares to LPC. No warrants, derivatives, financial or business covenants are associated with the Agreements, and LPC has agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of shares of the Company's common stock. The Agreements may be terminated by KemPharm at any time, at its sole discretion, without any cost or penalty.

A more detailed description of the Agreements is set forth in KemPharm's Current Report on Form 8-K as filed with the SEC.

"Entering into this facility with Lincoln Park Capital adds flexibility for KemPharm as we continue working to submit the NDA for KP415 and other supporting activities leading up to potential approval of KP415," said Dr. Mickle. "This strengthens our balance sheet as we seek the best possible outcome from the KP415/KP484 partnering process, and we believe it provides the potential to extend our cash runway up to a potential PDUFA date for KP415."

This press release does not constitute an offer to sell or a solicitation of an offer to buy the securities in this offering, nor will there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale are unlawful prior to registration or qualification under securities laws of any such jurisdiction.

#### **Conference Call Information:**

KemPharm will host a conference call and live audio webcast with slide presentation on Thursday, February 28, 2019, at 4:30 p.m. ET, to discuss its corporate and financial results for the fourth quarter and full year 2018. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 3286744

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 at approximately 5:30 p.m. ET, on February 28, 2019.

#### **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<sup>TM</sup> (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. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. In addition, KemPharm has received FDA approval for APADAZ<sup>®</sup>, 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](http://www.kempharm.com) or connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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**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.

**Investor/Media Contacts:**

Jason Rando / Joshua Drumm, Ph.D.

Tiberend Strategic Advisors, Inc.

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[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com)

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

	Year ended December 31,	
	2018	2017
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	41,759	20,593
General and administrative	12,508	12,773
Severance expense	1,636	—
Total operating expenses	55,903	33,366
Loss from operations	(55,903)	(33,366)
Other (expense) income:		
Gain on extinguishment of debt	2	—
Interest expense related to amortization of debt issuance costs and discount	(1,618)	(1,561)
Interest expense on principal	(5,469)	(5,776)
Fair value adjustment related to derivative and warrant liability	5,976	(3,091)
Interest and other income, net	420	365
Total other (expense) income	(689)	(10,063)
Loss before income taxes	(56,592)	(43,429)
Income tax benefit	126	43
Net loss	\$ (56,466)	\$ (43,386)
Net loss per share:		
Basic and diluted	\$ (3.15)	\$ (2.96)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	17,930,023	14,652,898

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

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,409	\$ 10,871
Marketable securities	3,260	31,358
Trade date receivables	—	2,005
Prepaid expenses and other current assets	2,052	1,662
Total current assets	23,721	45,896
Property and equipment, net	1,753	2,004
Long-term investments	—	3,250
Restricted cash	710	1,100
Other long-term assets	562	206
Total assets	\$ 26,746	\$ 52,456
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,342	\$ 7,875
Current portion of convertible notes	3,333	3,333
Current portion of capital lease obligation	214	189
Other current liabilities	115	112
Total current liabilities	12,004	11,509
Convertible notes, less current portion, net	78,105	89,398
Derivative and warrant liability	2,118	7,709
Capital lease obligation, less current portion	396	562
Other long-term liabilities	689	794
Total liabilities	93,312	109,972
Stockholders' deficit:		
Preferred stock:		
Series A convertible preferred stock, \$0.0001 par value, 9,578 shares authorized, 9,577 shares issued and 3,337 shares outstanding as of December 31, 2018; no shares authorized, issued or outstanding as of December 31, 2017	—	—
Undesignated preferred stock, \$0.0001 par value, 9,990,422 shares authorized, no shares issued or outstanding as of December 31, 2018; 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2017	—	—
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 26,455,352 shares issued and outstanding as of December 31, 2018; 14,657,430 shares issued and outstanding as of December 31, 2017	3	1
Additional paid-in capital	154,623	107,209
Accumulated deficit	(221,192)	(164,726)
Total stockholders' deficit	(66,566)	(57,516)
Total liabilities and stockholders' deficit	\$ 26,746	\$ 52,456



**KemPharm**

**Quarterly Update Call – Q4 and FY 2018**

**February 28, 2019**

## 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 potential fast-track, breakthrough or expedited FDA review, the potential advantages and/or clinical utility of our product candidates, the timing of NDA submissions, our intellectual property position, the commercial launch of APADAZ<sup>®</sup>, and the period over which we expect our existing financial resources to fund operating expenses and capital expenditure requirements. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018, and our other Periodic and Current Reports filed with the SEC. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Further, the information contained in this presentation speaks only as the date hereof. While we may elect to update the information in this presentation in the future, we disclaim any obligation to do so except to the extent required by applicable law.

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



## Quarterly Update 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**



## Key 2018 Highlights

### KP415

- ✓ KP415 pivotal efficacy program completed – July 2018
- ✓ KP415 prodrug human abuse potential trials completed – September 2018

### APADAZ®

- ✓ FDA approval – February 2018
- ✓ KVK Tech license agreement – October 2018

### LAT™ Value Enhancement

- ✓ twoXAR collaboration – October 2018
- ✓ KP879 product candidate introduction – November 2018

### Corporate/Financial

- ✓ Converted \$3.3M of principal on our senior secured convertible note – June 2018
- ✓ Completed public offering with net proceeds of approx. \$23.1M – October 2018
- ✓ Reduced debt by \$9.6M by exchange into preferred shares – October 2018





# Attention-Deficit/Hyperactivity Disorder:

**KP415 and KP484  
for the Treatment of ADHD**



## KP415 and KP484 Program Overview

- Two unique formulations of our prodrug of d-methylphenidate (serdexmethylphenidate, or SDX) addressing unmet needs within the ADHD market
- Composition-based patent expires in 2032; pending applications, if granted, may potentially expire in 2037; potentially NCE eligible; global patents issued
- Potential KP415 features and benefits
  - Once-daily dosing intended for most ADHD patients
  - Earlier onset and longer duration of therapeutic effect
  - Lower abuse potential
- Potential KP484 features and benefits
  - Once-daily dosing primarily for adults
  - Longer duration than other super-extended release ADHD products
  - Lower abuse potential



## KP415 Clinical Trial Summary

- Single, pivotal efficacy trial
  - ADHD classroom design
  - Efficacy trial met its primary endpoint
  - Secondary endpoints of SKAMP-C, PERMP-A and PERMP-C support 30-minute onset of effect with duration up to 13 hours
- SDX human abuse potential (HAP) trials
  - Statistically significant differences in key HAP endpoints were observed between SDX and active comparators for all routes of administration studied:
    - Oral
    - Intranasal
    - Intravenous
  - Required by FDA for scheduling recommendation and labeling



## KP415 & KP484 – Key Value Drivers

- NDA submissions
  - KP415 pre-NDA meeting delayed until Q2 2019 due to government shutdown
  - KP415 NDA submission to follow
  - KP484 NDA planned for 2020
- Strategic Partnering Process
  - Competitive process in late-stage discussions with a number of potential partners
  - Additional parties have joined the process since the December 2018 update
  - Previously engaged parties remain active
  - Partner discussions and diligence are focused on the market potential for KP415/KP484 and commercial implementation within each respective organization



**APADAZ<sup>®</sup>**

**FDA Approved for the Short-Term Treatment of  
Acute Pain**



## APADAZ® Product and License Overview

- First prodrug of hydrocodone (benzhydrocodone) combined with acetaminophen to be approved by the FDA with differentiated properties and long-lived patents
- Multiple strengths now approved providing maximum prescribing flexibility:
  - 4.08 mg benzhydrocodone HCl / 325 mg APAP
  - 6.67 mg benzhydrocodone HCl / 325 mg APAP
  - 8.16 mg benzhydrocodone HCl / 325 mg APAP
- Commercial license agreement with KVK-Tech, Inc.
  - KemPharm eligible to receive up to an estimated \$3.4M in pre-launch payments, milestones and cost reimbursements and additional milestone payments of up to \$53M tied to specified net sales levels
  - Net profit share of up to 50% between KemPharm and KVK
  - Most costs and responsibilities shift to KVK; KemPharm remains engaged to support KVK's commercial launch





## APADAZ® Launch Update

- Accelerate preparation and assistance for anticipated 2H 2019 APADAZ® commercial launch:
  - Technology and regulatory transfers (NDA) to KVK underway or complete
  - Manufacturing of commercial supply underway
  - Branded APADAZ and authorized generic now on compendia for all three approved strengths
  - Both products have pricing similar to generics
- Ongoing support of KVK's payor outreach efforts
  - Initiate regional pilot launches as early as 2H 2019
  - Outreach to a number of plans previously engaged in review of APADAZ as well as new plans through a broader outreach effort
  - Contract with and seek plan adoption for exclusive utilization of APADAZ as an alternative to currently available HC/APAP products in exchange for price parity with available generic products



**LAT™**

**Unlocking Multiple Opportunities  
to Create Long-Term Value**





## KemPharm Product Pipeline and Partnered Asset

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD	KP415	Methylphenidate (ER)	Clinical	NDA Submission	Q2 2019
	KP484	Methylphenidate (ER)	Clinical	Initiation of Efficacy Trial	2020
Stimulant Use Disorder	KP879	Methylphenidate (ER)	Preclinical	IND Submission	TBD
Partnered Asset	Apadaz®	Hydrocodone/ APAP	<b>FDA Approved</b>	Commercial Launch	N/A



## Stimulant Use Disorder (SUD)

- Stimulant Use Disorder (SUD) is broadly defined as the abuse or misuse of cocaine, methamphetamine, or other stimulants
- Although there are therapies for opioid addiction (buprenorphine, methadone), there are currently no approved treatments for SUD
- Studies with agonist replacement therapies have shown promising data for treating SUD

### U.S. Prevalence of Stimulant Abuse in 2016

	Stimulant Abuse Reported In Last 30 Days
Prescription Stimulants	1,700,000
Cocaine	1,900,000
Methamphetamine	<u>~ 700,000</u>
<b>Total:</b>	<b>4,300,000</b>

Source: Substance Abuse and Mental Health Services Administration. (2017). HHS Publication No. SMA 17-5044, NSDUH Series H-52.



## KP879 for the Treatment of SUD

- Potential KP879 features and benefits:
  - Stand-alone formulation of serdexmethylphenidate (SDX)
  - Releases d-methylphenidate, a dopamine reuptake inhibitor (similar pharmacology as abused stimulants)
  - Very gradual onset of blood concentrations of released d-methylphenidate followed by sustained release
  - Low oral, IN, and IV abuse potential
- Focus of initial clinical studies
  - High dose PK
  - High-dose safety
  - Effect size in different treatment populations
- May qualify for FDA fast track, breakthrough therapy and/or priority review
- May qualify for orphan designation depending on exact indication and target population



## 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)



# Financial Update



## Q4 2018 Financial Results

- Q4 2018 net loss of \$5.2M, or \$0.20 per basic share, and \$0.21 per diluted share, vs. Q4 2017 net loss of \$10.6M, or \$0.72 per basic and diluted share
  - Net loss for Q4 2018 primarily due to operating loss of \$9.3M and net interest expense and other items of \$1.6M, partially offset by non-cash fair value adjustment income of \$5.7M
  - Operating loss increased to \$9.3M for Q4 2018 compared to \$8.2M for Q4 2017, primarily due to increases of \$0.8M in R&D expenses and \$0.4M in G&A expenses, respectively





## FY 2018 Financial Results

- FY 2018 net loss of \$56.5M, or \$3.15 per basic and diluted share, vs. FY 2017 net loss of \$43.4M, or \$2.96 per basic and diluted share
  - Net loss for FY 2018 primarily due to operating loss of \$55.9M and net interest expense and other items of \$6.5M, partially offset by non-cash fair value adjustment income of \$6.0M
  - Operating loss increased to \$55.9M for FY 2018 compared to \$33.4M for FY 2017, primarily due to an increase of \$21.2M in R&D expenses and \$1.6M of severance expense in 2018, partially offset by a decrease of \$0.3M in G&A expense
- As of December 31, 2018, total cash and investments<sup>1</sup> were \$22.4M, which was an increase of \$8.3M compared to September 30, 2018
- Based on the current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements into, but not through, Q3 2019

<sup>1</sup> - Includes cash, cash equivalents, restricted cash and marketable securities



## Financial Update

- Added financial flexibility to execute on development and partnering strategy:
  - Completed an underwritten public offering of 8.3M shares in October 2018, receiving net proceeds of approx. \$23.1M
  - Reduced debt by \$9.6M via exchange into preferred shares
  - Entered into a \$15M equity line of credit (ELOC) facility with Lincoln Park Capital
  - Taken together, these additional resources as well as managing our cash burn rate potentially extend our cash runway up to KP415 approval
- Addressing long-term financial stability:
  - KP415/KP484 partnership opportunity
  - APADAZ commercial launch and revenue
  - Prodrug technology partnerships
  - Non-dilutive debt reduction





## KemPharm Value Proposition

### **KP415/KP484 provide near-term, potentially high value opportunities**

- Partnership
- NDA submission
- Approval
- Launch with partner into a large market

### **Building future value**

- KP879
- Value realization with other assets (i.e. APADAZ, other opioids)
- Continue to advance our development product pipeline
- R&D collaborations (i.e. twoXAR, Genco)

