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): October 30, 2018 (October 25, 2018)

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2500 Crosspark Road, Suite E126 **Coralville, IA** **(Address of Principal Executive Offices)**		**52241** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (319) 665-2575

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 1.01 Entry into a Material Definitive Agreement.

On October 25, 2018, KemPharm, Inc. (the "Company") entered into a Collaboration and License Agreement (the "Agreement") with KVK Tech, Inc. ("KVK"), pursuant to which the Company has granted an exclusive license to KVK to conduct regulatory activities for, manufacture and commercialize APADAZ®, the Company's product 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, in the United States.

Pursuant to the Agreement, KVK has agreed to pay the Company pre-launch payments and cost reimbursements of an estimated $3.4 million, which includes a pre-launch payment of $2.0 million within 10 days of the achievement of a specified milestone related to the initial formulary adoption of APADAZ (the "Initial Adoption Milestone"). In addition, KVK has agreed to make additional payments upon the achievement of specified sales milestones of up to $53.0 million in the aggregate. Further, the Company and KVK will share the quarterly Net Profits (as defined in the Agreement) of APADAZ by KVK in the United States at specified tiered percentages, ranging from the Company receiving 30% to 50% of Net Profits, based on the amount of Net Sales (as defined in the Agreement) on a rolling four quarter basis. The Company is responsible for a portion of commercialization and regulatory expenses for APADAZ until the Initial Adoption Milestone is achieved, after which KVK will be responsible for all expenses incurred in connection with commercialization and maintaining regulatory approval in the United States.

The Agreement will terminate on the later of the date that all of the patent rights for APADAZ have expired in the United States or KVK's cessation of commercialization of APADAZ in the United States. KVK may terminate the Agreement upon 90 days written notice if a regulatory authority in the United States orders KVK to stop sales of APADAZ due to a safety concern. In addition, after the third anniversary of the Agreement, KVK may terminate the Agreement without cause upon 18 months prior written notice. The Company may terminate the Agreement if KVK stops conducting regulatory activities for or commercializing APADAZ in the United States for a period of six months, subject to specified exceptions, or if KVK or its affiliates challenge the validity, enforceability or scope of any licensed patent under the Agreement. Both parties may terminate the Agreement (i) upon a material breach of the Agreement, subject to a 30-day cure period, (ii) the other party encounters bankruptcy or insolvency or (iii) if the Initial Adoption Milestone is not achieved. Upon termination, all licenses and other rights granted by the Company to KVK pursuant to the Agreement would revert to the Company.

The Agreement also establishes a joint steering committee, which will monitor progress in the development and commercialization of APADAZ.

The foregoing is a summary description of certain terms of the Agreement, is not complete and is qualified in its entirety by reference to the text of the Agreement, which the Company expects to file as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2018.

Item 3.02 Unregistered Sale of Equity Securities.

In connection with the Agreement, on October 25, 2018, the Company issued to KVK a warrant to purchase up to 500,000 shares of common stock of the Company at an exercise price of $2.30 share, which reflects the closing price of the Company's common stock on the Nasdaq Global Market on October 25, 2018 (the "Warrant"). The Warrant is initially not exercisable for any shares of common stock. Upon the achievement of each of four specified milestones under the Warrant, the Warrant will become exercisable for an additional 125,000 shares for each of the four specified milestones, up to an aggregate of 500,000 shares, of the Company's common stock. The exercise price and the number and type of shares underlying the Warrant are subject to adjustment in the event of specified events, including a reclassification of the Company's common stock, a subdivision or combination of the Company's common stock, or in the event of specified dividend payments. The Warrant is exercisable until October 24, 2023. Upon exercise, the aggregate exercise price may be paid, at KVK's election, in cash or on a net issuance basis, based upon the fair market value of the Company's common stock at the time of exercise.

The Warrant was offered and sold to KVK in a transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), or state securities laws, in reliance on Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D of the Securities Act and in reliance on similar exemptions under applicable state laws. KVK represented that it is an accredited investor within the meaning of Rule 501(a) of Regulation D and is acquiring the Warrant for investment purposes only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. The Warrant was offered without any general solicitation by the Company or its representatives.

The foregoing is a summary description of certain terms of the Warrant, is not complete and is qualified in its entirety by reference to the text of the Warrant, which the Company expects to file as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2018.

Item 7.01 Regulation FD Disclosure.

On October 30, 2018, the Company made available on the Company's website at www.kempharm.com an investor presentation on matters related to the Agreement and the APADAZ commercialization strategy.

A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the presentation furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act 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	Presentation titled "Management Presentation" dated October 30, 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: October 30, 2018

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

APADAZ® License Agreement with KVK Tech, Inc.

October 30, 2018

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, anticipated milestone and royalty payments, planned collaboration activities with our strategic partners, 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.

APADAZ® License Agreement 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

APADAZ® License Agreement

✓ **KemPharm enters into a definitive license agreement with KVK Tech, Inc. for the commercialization of APADAZ**

- KVK Tech 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 Tech
- Responsibility for API costs and other materials for manufacturing, validation batches, inventory investments and other launch-specific costs are shifted to KVK Tech

KVK Tech, Inc.

✓ **KVK Tech is one of the largest controlled substance manufacturers and distributors in the U.S.**

- Private company founded in 2004
- 12,000 square foot, state-of-the art controlled substance vault is one of the largest in the U.S.; capable of handing CI through CV products
- Current overall capacity of more than 3.5 billion tablets annually, and actively expanding capacity to more than 15 billion tablets by 2020
- Manufacturing expertise in oral solids/liquids, nasals, topicals and sterile injectables, ophthalmics and biologics; excellent compliance history and mastery of niche, high barrier-to-entry products
- Strong reputation for dependable, high-quality supply with limited stock-outs; winner of supplier of the year awards from key customers including Cardinal Health, Express Scripts, Econodisc and Optisource

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's Next Steps

- Accelerate preparation for anticipated 2H 2019 APADAZ® commercial launch
  - Begin technology transfer to KVK including transfer of NDA
  - KVK to initiate validation batches in preparation of commercial launch
  - Support KVK to initiate regional pilot launches as early as 2H 2019
- Assess KemPharm's opioid development pipeline
  - Oxycodone/APAP IR (generic Percocet®)
  - Oxycodone IR (generic Roxicodone®)
- Advance KemPharm's internally-developed candidate pipeline
- File KP415 NDA as early as Q1 2019
- Continue to focus on partnering KP415 and KP484

KemPharm

APADAZ® License Agreement with KVK Tech, Inc.

October 30, 2018