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 2, 2020

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

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL		**34747**
(Address of Principal Executive Offices)		**(Zip Code)**

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

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KMPH	Nasdaq Capital Market

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 7.01 Regulation FD Disclosure.

On March 2, 2020, KemPharm, Inc., or the Company, issued a press release to announce that the Company today submitted a New Drug Application for KP415, its investigational product candidate for the treatment of attention deficit hyperactivity disorder, to the U.S. Food and Drug Administration. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01, and the press release furnished as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "KemPharm Submits KP415 NDA to the FDA for the Treatment of ADHD" dated March 2, 2020.

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 2, 2020

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

KemPharm Submits KP415 NDA to the FDA for the Treatment of ADHD

If approved, KemPharm believes that KP415 may address several unmet needs, including earlier onset of action and longer duration of therapeutic effect vs. other available methylphenidate products

Celebration, FL – March 2, 2020 – KemPharm, Inc. (Nasdaq: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that it has submitted a New Drug Application (NDA) under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for its investigational product candidate, KP415, to the U.S. Food and Drug Administration (FDA). KP415 is KemPharm's product candidate for the treatment of attention deficit hyperactivity disorder (ADHD) which contains serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH).

Initially, the FDA will review the data package and, if deemed to be complete, will issue formal notice of acceptance of the submission, a process which typically takes sixty (60) days from the date of submission. Since KP415 contains SDX, which is a new molecular entity (NME), the FDA review guidance for NMEs is ten (10) months from the date of acceptance, which could lead to a potential action (PDUFA) date in March 2021.

"Submission of the KP415 NDA is a significant milestone for KemPharm as we seek FDA approval for our first ADHD product candidate based on our proprietary LAT™ prodrug technology," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "We believe the data package submitted with the NDA supports our conclusion that KP415 is effective in treating ADHD, has an onset of action at 30 minutes, has a duration of effect of 13 hours, and avoids unnecessary spikes in d-MPH concentrations that may be associated with adverse events. We also believe that the SDX component of KP415 may have lower abuse potential than relevant d-MPH comparators."

The KP415 NDA filing was prepared by KemPharm in collaboration with Gurnet Point Capital (GPC). In September 2019, KemPharm entered into a strategic licensing agreement with an affiliate of GPC, for the exclusive worldwide rights to develop, manufacture and, if approved, commercialize KemPharm's product candidates containing SDX, including KemPharm's ADHD product candidates, KP415 and KP484. The license agreement provides that a regulatory milestone payment will be payable to KemPharm thirty (30) days following FDA acceptance of the KP415 NDA.

"We look forward to working with the FDA as they complete their review of the KP415 NDA," Dr. Mickle concluded. "In addition, our work continues with GPC's commercial team as we now focus on preparing for the potential launch of KP415 in the U.S."

About KP415:

KP415 consists of SDX co-formulated with immediate-release d-MPH and is designed to address unmet needs with the most widely-prescribed methylphenidate ADHD treatments, including earlier onset of action and longer duration of therapy, while avoiding unnecessary spikes in d-MPH concentrations that may be associated with adverse events. In addition, results from the various Human Abuse Potential trials for the SDX component of KP415 suggest that the prodrug alone may have lower abuse potential than relevant d-MPH comparators.

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT™ (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT™ technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder. 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®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com or connect with us on Twitter, LinkedIn, Facebook and YouTube.

Caution Concerning Forward Looking Statements:

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation the Company's proposed development and commercial timelines, 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, including the probability of acceptance and potential FDA approval of the KP415 NDA, the potential commercial launch of KP415, and the potential clinical benefits of KP415 or any of our product candidates, 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, 2019, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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