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): May 4, 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 May 4, 2020, KemPharm, Inc., or the Company, issued a press release to announce that the Company confirmed that the U.S. Food and Drug Administration, or the FDA, accepted the Company's New Drug Application, or NDA, for KP415, the Company's investigational product candidate for the treatment of attention deficit hyperactivity disorder. In addition, the Company announced that Corium, Inc., a portfolio company of Gurnet Point Capital, will lead all commercialization activities for KP415, if approved. 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 8.01 Other Events.

On May 4, 2020, the Company announced that the FDA accepted the Company's NDA for KP415. Per the Company's definitive collaboration and license agreement with an affiliate of Gurnet Point Capital, the Company is entitled to receive a regulatory milestone payment of $5 million following the FDA's acceptance of the KP415 NDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "NDA Filing for Potential New ADHD Treatment, KP415, Accepted by FDA; KemPharm Eligible to Receive $5 Million Milestone Payment from Gurnet Point Capital" dated May 4, 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: May 4, 2020

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

Exhibit 99.1

NDA Filing for Potential New ADHD Treatment, KP415, Accepted by FDA; KemPharm Eligible to Receive $5 Million Milestone Payment from Gurnet Point Capital

Corium, GPC's portfolio company, to lead all commercialization activities for KP415

Celebration, FL – May 4, 2020 – KemPharm, Inc. (Nasdaq: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today confirmed that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for its investigational product candidate, KP415. Per the definitive collaboration and license agreement (the "License Agreement") between KemPharm and an affiliate of Gurnet Point Capital (GPC), KemPharm is eligible to receive a regulatory milestone payment of $5 million within thirty (30) days following FDA acceptance of the KP415 NDA.

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). 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.

In addition, KemPharm also announced that Corium, Inc. (Corium) will lead all commercialization activities for KP415, if approved. Corium is a portfolio company of GPC focused on the development, manufacture and commercialization of specialty pharmaceutical products. Corium is led by Perry Sternberg, its President and CEO, who is a biotechnology and pharmaceutical industry leader with more than 25 years of commercial experience across a wide range of therapeutic areas in diverse markets. Prior to joining Corium, Mr. Sternberg served a dual role at Shire Plc (Shire) as the Head of U.S. Commercial for seven therapeutic area business units, as well as the Chief Commercial Officer/Head of the Neuroscience Division, before the acquisition of Shire by Takeda Pharmaceutical Corporation Limited in early 2019.

"We are pleased that the FDA has accepted the KP415 NDA, and we now look forward to working with the team at GPC to advance the regulatory review process towards a potential approval as early as March 2021," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "In addition to the regulatory activities, we are thrilled to have the opportunity to benefit from Perry's leadership and Corium's commercialization expertise to bring this new treatment to market, following FDA approval."

Mr. Sternberg stated, "The advances KemPharm is making in the treatment of ADHD are exciting. There are several unmet needs with existing treatment options, which we believe KP415 has the potential to address, bringing meaningful benefits to physicians, patients and their families. The team at Corium is energized to be working with KemPharm to advance KP415 towards a potential approval and launch."

In September 2019, KemPharm entered into the License 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. In addition to the $5 million regulatory milestone payment for acceptance of the KP415 NDA, the License Agreement also provides for a regulatory milestone payment within thirty (30) days after approval of the KP415 NDA.

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.

About Gurnet Point Capital:

Gurnet Point Capital is a unique healthcare fund founded by Ernesto Bertarelli and led by Chris Viehbacher, who, together, have decades of expertise in an industry for which they share a passion, both as Chief Executives and as investors. With an initial allocation of $2 billion, GPC is investing long-term capital and supporting entrepreneurs in building a new generation of companies. Based in Cambridge, MA, its remit is global, encompassing life sciences and medical technologies. The fund invests across all stages of product development through to commercialization and does so with an approach that is a hybrid of venture and private equity investing strategies. www.gurnetpointcapital.com

About Corium:

Corium, Inc. is a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage the company's broad experience with advanced transdermal and transmucosal delivery systems. Corium has developed and is the sole commercial manufacturer of seven prescription drug and consumer products with partners including Mayne Pharma and Procter & Gamble. The company has two proprietary transdermal platforms: Corplex for small molecules and MicroCor®, a biodegradable microstructure technology for small molecules and biologics, including vaccines, peptides and proteins. In November 2018, all of Corium's outstanding stock was acquired by an affiliate of Gurnet Point Capital. For further information, please visit www.coriumintl.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, 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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