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 14, 2019

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))

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 May 14, 2019, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended March 31, 2019. A copy of the press release is furnished as Exhibits 99.1 to this Current Report on Form 8-K. The information contained in the press release, furnished as Exhibits 99.1, 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 Securities 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	Press Release titled "KemPharm Reports First Quarter 2019 Results" dated May 14, 2019.

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 14, 2019

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

EXHIBIT 99.1

KemPharm Reports First Quarter 2019 Results

Development & Regulatory Highlights:

- Completed KP415 Pre-NDA Meeting with FDA
- Provided Update on APADAZ® Formulary Adoption
- Announced FDA Approval of sNDA for Two Additional Strengths of APADAZ

Corporate & Financial Highlights:

- Q1 2019 net loss of $0.46 per basic and diluted share
- Total cash, cash equivalents and restricted cash was $14.0 million at March 31, 2019
- Partnering process for ADHD franchise entering final stages

Celebration, FL – May 14, 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 ended March 31, 2019.

"The first quarter of 2019 and early April were highlighted by advancements in our KP415 and APADAZ® programs, serving to propel each towards what we believe will be significant value building events in the coming months," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "For KP415, our prodrug product candidate being developed for the treatment of attention-deficit/hyperactivity disorder (ADHD), we announced the completion of the pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA). We have recently received the minutes from that meeting which confirm the previously reported results. In summary, we believe the review of the KP415 pre-NDA briefing package, which included clinical, non-clinical and human abuse potential study results, as well as regulatory elements, was consistent with our interpretation and previous interactions with the FDA, and, as a result, we believe that we are positioned to submit the KP415 NDA in late second quarter or early third quarter 2019."

"In parallel with the regulatory activities for KP415, we have entered into what we believe are the final stages of the partnering process for our ADHD franchise, which includes KP415 and KP484," continued Dr. Mickle. "Since the initiation of the partnering process, our goal has been focused on securing an agreement with a partner fully dedicated to maximizing the commercial value of KP415 and KP484. While still engaged with multiple parties, we believe that the process should be complete sometime later this quarter or early third quarter."

"With regard to APADAZ, we continue to work with our partner, KVK Tech, to advance several initiatives that we believe will contribute to a successful market introduction of the product. The commercial launch remains on track for the second half of 2019," said Dr. Mickle. "The first quarter was highlighted by three important events. In January, we received FDA approval of two additional dosage strengths of APADAZ. Following that, in February, APADAZ was added to compendia with authorized generic pricing similar to current generics. And most recently, beginning in March, we learned that the ongoing process of formulary adoption of APADAZ and its authorized generic had advanced more rapidly than we anticipated. Notably, according to Managed Markets Insights and Technology estimates, APADAZ, both the brand and authorized generic, is currently being reviewed and added to formularies in various markets including both commercial and Medicaid. Based on this progress and other indicators, we continue to believe that the replacement of current hydrocodone/acetaminophen (APAP) products with APADAZ and its authorized generic has the potential to be a meaningful market opportunity."

Q1 2019 Financial Results:

For the quarter ended March 31, 2019, KemPharm's reported net loss was $12.3 million, or $0.46 per basic and diluted share, compared to a net loss of $26.2 million, or $1.77 per basic and diluted share for the same period in 2018. Net loss for Q1 2019 was driven primarily by an operating loss of $11.4 million and net interest expense and other items of $1.4 million, partially offset by non-cash fair value adjustment income of $0.5 million. The operating loss of $11.4 million for Q1 2019 was a decrease of $3.4 million compared to $14.8 million in Q1 2018, which was primarily due to decreases of $3.1 million in research and development expenses and $0.3 million in general and administrative expenses, respectively.

As of March 31, 2019, total cash, which is comprised of cash, cash equivalents and restricted cash, was $14.0 million, which was a decrease of $8.4 million as compared to December 31 2018. The decrease in total cash during Q1 2019 was due to a use of cash of $11.1 million, offset by proceeds of $2.7 million on the sale of approximately 1.4 million shares under the equity line of credit with Lincoln Park Capital.

"As we seek to finalize the partnering process for KP415 and KP484, we have utilized a portion of our equity line of credit with Lincoln Park Capital. This additional capital, combined with cost reductions, extends the cash runway further into Q3 2019," said Dr. Mickle. "In addition, we expect that our cash burn rate will reduce substantially following the NDA filing for KP415."

Presentation and Webcast at RBC Capital Markets Global Healthcare Conference:

KemPharm also announced today that Dr. Mickle will present at the RBC Capital Markets 2019 Global Healthcare Conference being held May 21-22, 2019, at the InterContinental New York Barclay.

Details of KemPharm's presentation are as follows:

Event:	RBC Capital Markets 2019 Global Healthcare Conference
Date:	Wednesday, May 22, 2019
Time:	1:35 PM (EST)
Room:	Morgan Suite
Location:	InterContinental New York Barclay, 111 East 48th Street, New York, NY

The presentation will be webcast and available one hour following the live event at http://www.veracast.com/webcasts/rbc/healthcare2019/82314394157.cfm. The replay will be available for 90 days.

In addition, the presentation will be available on the Investor Relations section of the Company's website at http://investors.kempharm.com/.

Recent and Q1 2019 Activities:

- **Announced Completion of KP415 Pre-NDA Meeting with FDA**

  On April 11, 2019, KemPharm announced that it concluded a pre- NDA meeting with the FDA for KP415, KemPharm's investigational attention-deficit/hyperactivity disorder (ADHD) product candidate that contains serdexmethylphenidate (SDX, a prodrug of d-methylphenidate) and d-methylphenidate. At the pre-NDA meeting, representatives from the FDA reviewed KemPharm's summary of the data package being prepared for the KP415 NDA submission, including clinical, non-clinical and human abuse potential studies, as well as regulatory elements. Based on the feedback from the FDA, the Company believes its regulatory data package will be sufficient for submission, with acceptance of the filing subject to the FDA's review of the complete package.

- **Provided Update on APADAZ Formulary Adoption**

  On March 13, 2019, KemPharm provided an update on formulary adoption of APADAZ, an immediate release combination of KemPharm's prodrug, benzhydrocodone, and APAP. APADAZ and its authorized generic are currently being reviewed and added to formularies in various markets including Medicaid. KemPharm believes the continued adoption of APADAZ by formularies is another stepping stone in the efforts to prepare APADAZ for commercial launch as soon as the second half of this year.

- **Announced Enhancements to U.S. and Global Intellectual Property Estate, Including IP Protection for KP415 in Canada, Japan and Korea**

  On January 29, 2019, KemPharm announced enhancements to its U.S. and global intellectual property estate governing its portfolio of prodrug product candidates. The United States Patent and Trademark Office issued seven (7) new patents to KemPharm during 2018 related to several of its compound families, including KP201, KP303, KP511, KP606 and KP746. In addition, KemPharm has augmented and strengthened the global patent estate for KP415 with the addition of issued patents last year in Canada, Japan and Korea.

- **Presented Scientific Posters at APSARD's 2019 Annual Meeting**

  On January 18, 2019, KemPharm announced that research assessing the oral and intranasal human abuse potential of SDX, KemPharm's prodrug of d-methylphenidate (d-MPH), as well as new pharmacokinetic data for KP415, were presented in four posters and one oral "data blitz session" at the 2019 Annual Meeting of the American Professional Society for ADHD and Related Disorders (APSARD).

- **Announced FDA Approval of sNDA for Two Additional Strengths of APADAZ (4.08 mg benzhydrocodone/325 mg APAP and 8.16 mg benzhydrocodone/325 mg APAP**

  On January 7, 2019, KemPharm announced that the FDA approved a Supplemental New Drug Application (sNDA) for two additional strengths of APADAZ. The approval of these new dosage strengths, 4.08 mg benzhydrocodone/325 mg APAP and 8.16 mg benzhydrocodone/325 mg APAP, follows the NDA approval on February 23, 2018 of the 6.12 mg benzhydrocodone/325 mg APAP dosage strength of APADAZ.

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 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®, 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, 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, 2018, 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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KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2019	**2018**
Revenue	$ —	$ —
Operating expenses:		
Research and development	8,531	11,637
General and administrative	2,838	3,132
Total operating expenses	11,369	14,769
Loss from operations	(11,369)	(14,769)
Other (expense) income:		
Interest expense related to amortization of debt issuance costs and discount	(305)	(390)
Interest expense on principal	(1,229)	(1,442)
Fair value adjustment related to derivative and warrant liability	453	(9,741)
Interest and other income, net	151	115
Total other (expense) income	(930)	(11,458)
Loss before income taxes	(12,299)	(26,227)
Income tax benefit	8	8
Net loss	$ (12,291)	$ (26,219)
Net loss per share:		
Basic and diluted	$ (0.46)	$ (1.77)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	26,701,891	14,791,882

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

	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,438	$ 18,409
Marketable securities	—	3,260
Prepaid expenses and other current assets	1,873	2,052
Total current assets	15,311	23,721
Property and equipment, net	1,688	1,753
Operating lease right-of-use assets	1,785	—
Restricted cash	528	710
Other long-term assets	555	562
Total assets	$ 19,867	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,178	$ 8,342
Current portion of convertible notes	6,370	3,333
Current portion of capital lease obligation	—	214
Current portion of operating lease liabilities	395	—
Other current liabilities	229	115
Total current liabilities	15,172	12,004
Convertible notes, less current portion, net	75,373	78,105
Derivative and warrant liability	1,665	2,118
Capital lease obligation, less current portion	—	396
Operating lease liabilities, less current portion	2,142	—
Other long-term liabilities	351	689
Total liabilities	94,703	93,312
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 March 31, 2019 (unaudited) and December 31, 2018	—	—
Undesignated preferred stock, $0.0001 par value, 9,990,422 shares authorized, no shares issued or outstanding as of March 31, 2019 (unaudited) and December 31, 2018	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 27,976,823 shares issued and outstanding as of March 31, 2019 (unaudited); 26,455,352 shares issued and outstanding as of December 31, 2018	3	3
Additional paid-in capital	158,644	154,623
Accumulated deficit	(233,483)	(221,192)
Total stockholders' deficit	(74,836)	(66,566)
Total liabilities and stockholders' deficit	$ 19,867	$ 26,746