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, 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 2.02 Results of Operations and Financial Condition.

On February 28, 2020, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in 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, or the Exchange Act, and is not incorporated by reference into any of KemPharm's 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 Fourth Quarter and Full-Year 2019 Financial Results" dated February 28, 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: February 28, 2020

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

KemPharm Reports Fourth Quarter and Full-Year 2019 Financial Results

KP415 NDA Remains on Track for Q1 2020 Submission

Celebration, FL – February 28, 2020 – KemPharm, Inc. (Nasdaq: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today provided an update on the KP415 NDA and reported its financial results for the fourth quarter and full-year ended December 31, 2019.

"Our highest priority at KemPharm is filing the New Drug Application (NDA) for KP415, our prodrug product candidate of d-methylphenidate (d-MPH) being developed for the treatment of attention deficit hyperactivity disorder (ADHD)," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "During the last several months, we have been working hand-in-hand with the team of advisors assembled by our partner, Gurnet Point Capital (GPC), with the primary goal of submitting the best NDA for review by the FDA (U.S. Food and Drug Administration). We believe this investment in time and additional review will improve the probability of acceptance and subsequent approval of KP415 with the best possible label. The timing for the filing of the KP415 NDA is subject to the discretion of GPC and we anticipate receiving their approval to proceed shortly. We intend to file as soon as possible and remain on track to submit the NDA this quarter."

Dr. Mickle continued, "Once the KP415 NDA is submitted to the FDA, our full attention will be focused on ensuring a successful completion of the regulatory review process with the goal of achieving approval for KP415 with the broadest label. KP415 has the potential to be the first truly differentiated methylphenidate-based product introduced to the ADHD market in several years. This market accounted for approximately $3.9 billion in sales in 2018, and we believe KP415's potential attributes, including onset of action at 30 minutes, duration of effect of 13 hours, and substantially lower abuse potential than relevant d-methylphenidate comparators, could provide a solution to these unmet needs that have been repeatedly cited by both patients and prescribers."

Q4 and FY 2019 Financial Results:

For Q4 2019, KemPharm reported revenue of $1.4 million from research and development services, as compared to Q3 2019 revenue of $11.5 million, which was comprised of a one-time upfront payment of $10 million under the KP415 License Agreement (as defined below), and research and development services revenue of $1.5 million. This is KemPharm's second sequential quarter reporting research and development services revenue, and the Company expects this trend to continue as the Company provides services to GPC and its affiliates under the license agreement by and between KemPharm and Commave Therapeutics, S.A., an affiliate of GPC, dated September 3, 2019 (the KP415 License Agreement).

KemPharm's net loss for Q4 2019 was $6.0 million, or $0.18 per basic share and diluted share, compared to a net loss of $5.2 million, or $0.20 per basic and diluted share for the same period in 2018. Net loss for Q4 2019 was driven primarily by an operating loss of $4.4 million and net interest expense and other items of $1.8 million. The net operating loss of $4.4 million for Q4 2019 was a decrease of $4.9 million compared to $9.3 million in the same period in 2018, which was primarily due to revenue of $1.4 million, a decrease in research and development expenses of $3.8 million and a decrease in general and administrative expenses of $1.6 million, offset by royalty and direct contract acquisition costs of $1.9 million.

For FY 2019, revenue totaled $12.8 million, which is comprised of the $10.0 million upfront payment under the KP415 License Agreement, and research and development services revenue of $2.8 million. KemPharm's reported net loss was $24.5 million, or $0.83 per basic and diluted share, compared to a net loss of $56.5 million, or $3.15 per basic and diluted share for the year ended December 31, 2018. FY 2019 net loss was driven primarily by operating loss of $20.3 million and net interest expense and other items of $6.2 million, partially offset by non-cash fair value adjustment income of $2.0 million. Operating loss for FY 2019 of $20.3 million was a decrease of $35.6 million compared to the FY 2018 operating loss of $55.9 million, which was primarily due to FY 2019 revenue of $12.8 million, a decrease in research and development expenses of $22.3 million, a decrease in general and administrative expenses of $1.7 million, and a decrease in severance expense of $1.6 million, offset by royalty and direct contract acquisition costs of $2.9 million.

As of December 31, 2019, total cash and investments, which is comprised of cash, cash equivalents, and restricted cash, was $3.6 million, which was a decrease of $3.4 million compared to September 30, 2019. Based on the Company's current operating forecast, existing resources are sufficient to continue operations into, but not through Q3 2020. Existing resources combined with the potential milestones and revenue under the KP415 License Agreement have the potential to extend the cash runway into, but not through, Q1 2021.

"The measures we have taken to reduce our operating spend and restructure our debt obligations, as well as the potential milestones and revenue under the KP415 License Agreement, potentially extend our cash runway into, but not through, Q1 2021," stated LaDuane Clifton, KemPharm's Chief Financial Officer. "We expect research and development services revenue to continue through FY 2020 and beyond as we provide consultation services to support our partner in their commercial preparation activities for KP415 and with the potential initiation of the product development plan for KP484."

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 our 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 submission timing, probability of acceptance and potential FDA approval of the KP415 NDA, the potential commercial launch of KP415, the expectations regarding continued research and development services revenue, the potential clinical benefits of KP415 or any of our product candidates, cash runway and the ability to continue as a going concern, 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.

KemPharm Contacts:

Jason Rando / Maureen McEnroe
Tiberend Strategic Advisors, Inc.
212-375-2665 / 2664
jrando@tiberend.com
mmcenroe@tiberend.com

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

	Year Ended December 31,	
	2019	**2018**
Revenue	$ 12,839	$ -
Operating expenses:		
Royalty and direct contract acquisition costs	2,945	-
Research and development	19,415	41,759
General and administrative	10,816	12,508
Severance expense	-	1,636
Total operating expenses	33,176	55,903
Loss from operations	(20,337)	(55,903)
Other (expense) income:		
Gain on extinguishment of debt	-	2
Interest expense related to amortization of debt issuance costs and discount	(1,656)	(1,618)
Interest expense on principal	(4,858)	(5,469)
Fair value adjustment related to derivative and warrant liability	1,998	5,976
Interest and other income, net	309	420
Total other (expense) income	(4,207)	(689)
Loss before income taxes	(24,544)	(56,592)
Income tax benefit	22	126
Net loss	$ (24,522)	$ (56,466)
Net loss per share of common stock:		
Basic and diluted	$ (0.83)	$ (3.15)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	29,654,968	17,930,023

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

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,217	$ 18,409
Marketable securities	-	3,260
Accounts and other receivables	1,865	140
Prepaid expenses and other current assets	1,552	1,912
Total current assets	6,634	23,721
Property and equipment, net	1,471	1,753
Operating lease right-of-use assets	1,537	-
Restricted cash	338	710
Other long-term assets	527	562
Total assets	$ 10,507	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,911	$ 8,342
Current portion of convertible notes	-	3,333
Current portion of capital lease obligation	-	214
Current portion of operating lease liabilities	284	-
Other current liabilities	236	115
Total current liabilities	5,431	12,004
Convertible notes, less current portion, net	77,343	78,105
Derivative and warrant liability	120	2,118
Capital lease obligation, less current portion	-	396
Operating lease liabilities, less current portion	1,901	-
Other long-term liabilities	168	689
Total liabilities	84,963	93,312
Commitments and contingencies (Note H)		
Stockholders' deficit:		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2019; 9,577 shares issued and 3,337 shares outstanding as of December 31, 2018	-	-
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and no shares outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	-	-
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of December 31, 2019; no shares authorized, issued or outstanding as of December 31, 2018	-	-
Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2019; 9,990,422 shares authorized, no shares issued or outstanding as of December 31, 2018	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 36,350,785 shares issued and outstanding as of December 31, 2019; 26,455,352 shares issued and outstanding as of December 31, 2018	4	3
Additional paid-in capital	171,254	154,623
Accumulated deficit	(245,714)	(221,192)
Total stockholders' deficit	(74,456)	(66,566)
Total liabilities and stockholders' deficit	$ 10,507	$ 26,746