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): November 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))

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 Global 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 November 14, 2019, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended September 30, 2019, as well as information regarding a conference call and live audio webcast with slide presentation to discuss these corporate and financial results. A copy of the press release and presentation are furnished as Exhibit 99.1 and 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and presentation, furnished as Exhibit 99.1 and 99.2, respectively, 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 Third Quarter 2019 Results” dated November 14, 2019.
99.2	Presentation titled "Q3 2019 Results" dated November 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: November 14, 2019

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

Exhibit 99.1

KemPharm Reports Third Quarter 2019 Results

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for
Today, November 14, 2019, at 5:30 p.m. ET

Celebration, FL – November 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 September 30, 2019.

"The third quarter of 2019 was highlighted by our entry into a licensing agreement (the KP415/KP484 Licensing Agreement) with an affiliate of Gurnet Point Capital (GPC) for our ADHD product candidates, KP415 and KP484," said Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "Working with the team that GPC has assembled, our immediate focus remains on finalizing the New Drug Application (NDA) for KP415, with the goal of filing in January 2020, or sooner if possible. However, the decision of when to file belongs to GPC."

Dr. Mickle continued, "Since our last announcement, KVK-Tech, Inc. (KVK-Tech) has informed us that APADAZ® (benzhydrocodone and acetaminophen, or APAP, tablets) and its authorized generic, APADAZ-AG, are now available for wholesalers to place initial stocking orders. We look forward to further updates from our partner, KVK-Tech, as they begin their awareness efforts."

Q3 2019 Financial Results:

"Since the beginning of 2019, we have undertaken measures to reduce our operating spend, including a 33% workforce reduction, other general and administrative cost reductions, and the conclusion of the clinical phase for KP415. The KP415/KP484 License Agreement provides several milestone payments, including the $10M upfront payment we have already received, another milestone payable at acceptance of the KP415 NDA, potential regulatory milestones at approval and sales milestones post-approval. In addition, development cost reimbursements and consultation fee revenue for our support of all KP415 remaining development and commercial manufacturing provides the potential for us to cover a substantial portion of our operating expenses," said LaDuane Clifton, KemPharm's Chief Financial Officer.

For Q3 2019, KemPharm reported revenue of $11.5 million, which included the $10 million upfront payment, development cost reimbursements and consultation fee revenue generated under the KP415/KP484 License Agreement. Net income for Q3 2019 was $3.1 million, or $0.09 per basic share and $0.06 per diluted share, compared to a net loss of $15.1 million, or $0.94 per basic and diluted share for Q3 2018. Net income for Q3 2019 was driven primarily by income from operations of $3.2 million and non-cash fair value adjustment income of $1.4 million which was offset by net interest expense and other expenses of approximately $1.5 million. Research and development expenses for Q3 2019 were $3.6 million, which was a reduction of 73% compared to $13.3 million in Q3 2018. General and administrative expenses for Q3 2019 were $3.6 million, which was an increase of $0.6 million compared to Q3 2018, primarily driven by an increase in professional fees incurred in connection with the KP415 licensing process and partially offset by a decrease in personnel costs.

As of September 30, 2019, total cash, which is comprised of cash, cash equivalents and restricted cash, was $7.0 million. Based on our current operating forecast, which includes principal and interest payments totaling approximately $9.2 million, which are due in the first half of 2020, currently available resources are sufficient to continue operations into but not through Q2 2020.

“We continue to explore additional options to reduce our near-term cash requirements, including pushing out the timing of upcoming near-term principal and interest payments with the goal of extending our cash runway past the potential approval of the KP415 NDA. In addition, we have initiated a process to explore addressing our debt in its entirety. For that purpose, we have engaged Cowen and Company, LLC, to serve as our financial advisors,” Mr. Clifton concluded. While the Company is actively pursuing debt restructuring efforts, it cannot guarantee that those efforts will be successful for either the near- or long-term debt obligations.

The Company also reported that it expects to receive a notification from the Nasdaq Stock Market (Nasdaq) pertaining to its non-compliance with Nasdaq continued listing qualifications. Once received, the Company plans to submit a request to appear before the Nasdaq Hearings Panel and request an extension of the compliance period. Under Nasdaq rules, the Hearings Panel has the authority to extend the compliance period for up to an additional 180 days, subject to their review of the Company’s plan for regaining compliance with the continued listing requirements. During this process, KemPharm’s common stock would remain listed and active on the Nasdaq Global Market. There can be no assurance that the Company will be successful in maintaining the listing of its common stock on the Nasdaq Global Market.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation today, Thursday, November 14, 2019, at 5:30 p.m. ET, to discuss its corporate and financial results for the third quarter 2019. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 8076615

An audio webcast with slide presentation will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available for 90 days beginning at approximately 6:30 p.m. ET, on November 14, 2019.

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, 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. These include statements about development and potential commercialization of KP415 and KP484, and our efforts to restructure debt and the potential outcomes of those efforts. 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 September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 11,463	$ —	$ 11,463	$ —
Operating expenses:				
Cost of revenue	1,000	—	1,000	—
Research and development	3,616	13,330	16,950	35,455
General and administrative	3,613	2,992	9,440	9,544
Severance expense	—	1,636	—	1,636
Total operating expenses	8,229	17,958	27,390	46,635
Income (loss) from operations	3,234	(17,958)	(15,927)	(46,635)
Other (expense) income:				
Interest expense related to amortization of debt issuance costs and discount	(371)	(326)	(981)	(1,106)
Interest expense on principal	(1,208)	(1,367)	(3,669)	(4,228)
Fair value adjustment related to derivative and warrant liability	1,351	4,468	1,783	289
Interest and other income, net	60	52	295	290
Total other (expense) income	(168)	2,827	(2,572)	(4,755)
Income (loss) before income taxes	3,066	(15,131)	(18,499)	(51,390)
Income tax benefit	(3)	60	14	107
Net income (loss)	$ 3,063	$ (15,071)	$ (18,485)	$ (51,283)
Net income (loss) per share:				
Basic	$ 0.09	$ (0.94)	$ (0.65)	$ (3.33)
Diluted	$ 0.06	$ (0.94)	$ (0.65)	$ (3.33)
Weighted average number of shares of common stock outstanding:				
Basic	30,126,704	16,033,923	28,417,450	15,385,663
Diluted	31,672,149	16,033,923	28,417,450	15,385,663

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

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 6,518	$ 18,409
Marketable securities	—	3,260
Accounts and other receivables	1,638	140
Prepaid expenses and other current assets	528	1,912
Total current assets	8,684	23,721
Property and equipment, net	1,541	1,753
Operating lease right-of-use assets	1,649	—
Restricted cash	490	710
Other long-term assets	526	562
Total assets	$ 12,890	$ 26,746
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,095	$ 8,342
Current portion of convertible notes	6,718	3,333
Current portion of capital lease obligation	—	214
Current portion of operating lease liabilities	369	—
Other current liabilities	227	115
Total current liabilities	10,409	12,004
Convertible notes, less current portion, net	70,553	78,105
Derivative and warrant liability	335	2,118
Capital lease obligation, less current portion	—	396
Operating lease liabilities, less current portion	1,976	—
Other long-term liabilities	237	689
Total liabilities	83,510	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 September 30, 2019 (unaudited) and December 31, 2018	—	—
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and 789 shares outstanding as of September 30, 2019 (unaudited); 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 September 30, 2019 (unaudited); 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 September 30, 2019 (unaudited); 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, 32,387,382 shares issued and outstanding as of September 30, 2019 (unaudited); 26,455,352 shares issued and outstanding as of December 31, 2018	3	3
Additional paid-in capital	169,054	154,623
Accumulated deficit	(239,677)	(221,192)
Total stockholders' deficit	(70,620)	(66,566)
Total liabilities and stockholders' deficit	$ 12,890	$ 26,746


KemPharm
Q3 2019 Results
November 14, 2019

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about any royalty or milestone payments under our license agreement, the exchange of any future principal under our exchange agreement, our plans to develop and commercialize our product candidates, 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 November 14, 2019, 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.

Q3 2019 Results 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

Q3 2019 Results Call – Today's Updates

- KP415 NDA Timelines and Partnership with GPC
- APADAZ® Launch Update
- Q3 2019 Financial Results
- Cash Runway and Near-Term Debt Obligations
- Addressing the Debt Obligations
- Next Steps

KP415 NDA Timelines and Partnership Update

- Since license signing, GPC has:
  - Assembled a team of experienced advisors
  - Performed an initial review of every NDA section
  - Currently working with us to finalize the KP415 NDA
- Mutual goal for both organizations is the KP415 NDA filing ASAP
  - NDA should have a reasonably high probability of being accepted for review and approved with the best possible label
  - Current plan with GPC is to file the KP415 NDA around January 2020
  - Timing ultimately decided by GPC
- Commercial planning and preparations well underway
  - KemPharm managing commercial validation and manufacturing
  - Expect to update our partner's commercial activities when possible

APADAZ® Launch

- Since our October 31st update, KVK has reported to us that the product is now available for wholesalers to place initial stocking orders.
- Managed Market efforts are ongoing
- KVK is beginning efforts to make pharmacies and physicians aware that APADAZ is now available.
- KVK license agreement includes:
  - $2M milestone based on reaching a certain level of initial formulary adoption and corresponding estimates of potential annual utilization; potentially achievable in 2020
  - Reimbursements of up to $1.4M for commercial prep costs
  - Profit-share of up to 50%

Q3 2019 Financial Results

- Revenue and net income
  - Q3 2019 revenue of $11.5M
  - Net income of $3.1 million, or $0.09 per basic share and $0.06 per diluted share
- Expense
  - R&D expenses for Q3 2019 were $3.6M, a reduction of 73% compared to Q3 2018
  - G&A expenses for Q3 2019 were $3.6M, which was $0.6M more than Q3 2018, driven by an increase of professional fees related to the licensing process and offset by a decrease in personnel costs.
- At September 30, 2019, total cash[1] was $7.0M

1 - Includes cash, cash equivalents and restricted cash.

Cash Runway and Near-Term Debt Obligations

- Since the beginning of 2019, we have reduced operating spend:
  - Workforce reduction of 33% and other G&A cost reductions
  - Conclusion of the clinical phase for KP415
- In the near-term, cash from the KP415/KP484 License Agreement includes:
  - Milestone payments upfront and at acceptance of KP415 NDA
  - Development cost reimbursements for KP415
  - Consultation fee revenue for work on KP415 development and management of commercial manufacturing
- Current cash runway into but not through Q2 2020 based on current operating forecast which includes principal and interest payments totaling approximately $9.2M and due in first half of 2020

Addressing the Debt Obligations

- Currently in negotiations to push out near-term principal and interest payments due in Feb 2020 and June 2020
  - Goal is to extend cash runway past the potential approval of KP415
  - If successful, cash burn could be less than $1M per quarter for 2020
- Initiated a process to address our debt in its entirety
  - Engaged Cowen and Company, LLC as our financial advisor
  - Initial goal to adjust near-term debt obligations prior to Feb 2020 with the goal to address the larger portion of the debt prior to a potential KP415 approval

Next Steps

- Maximize the value of our license agreements for both KP415/KP484 and APADAZ
- File the KP415 NDA as soon as possible
- Seek to push-out near-term debt obligations and extend cash runway
- Meaningfully address debt with the best possible outcome