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 13, 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

Not Applicable
(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 7.01 Regulation FD Disclosure.

On March 13, 2019, KemPharm, Inc., or the Company, issued a press release to provide a commercial update on APADAZ® formulary adoption, as well as information regarding a conference call and live audio webcast with slide presentation to discuss this corporate update. 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 this Item 7.01, and the press release and presentation furnished as Exhibits 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, and is 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 Provides Update on APADAZ® Formulary Adoption" dated March 13, 2019.
99.2	Presentation titled "APADAZ® Commercial Update Call" dated March 13, 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: March 13, 2019

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

Exhibit 99.1

KemPharm Provides Update on APADAZ® Formulary Adoption

Conference Call Scheduled for Today, Wednesday, March 13, 2019 at 8:30 a.m. ET

Highlights:

- According to MMIT estimates, the authorized generic for APADAZ has unrestricted formulary access for 91% of Commercial lives and unrestricted access for 90% of state Medicaid lives
- According to MMIT estimates, branded APADAZ® has unrestricted formulary access for 15% of Commercial lives

Celebration, FL – March 13, 2019 – KemPharm, Inc. (Nasdaq: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today provided an update on formulary adoption of its FDA-approved prodrug product, APADAZ® (benzhydrocodone and acetaminophen, or APAP, tablets), which has been licensed to KVK-Tech, Inc. for commercialization. According to Managed Markets Insights and Technology (MMIT, www.formularylookup.com) estimates, the authorized generic of APADAZ (benzhydrocodone/APAP, or AG-APADAZ) currently has unrestricted formulary access for 91% of Commercial lives and unrestricted access for 90% of state Medicaid lives. In addition, MMIT estimates indicate that branded APADAZ currently has unrestricted formulary access for 15% of Commercial lives, generally at a Tier 3 or equivalent reimbursement status.

Based on 2018 utilization data for hydrocodone/APAP (HC/APAP), the total market was nearly four billion tablets, of which 41% was Commercial, 39% was Medicare, and 12% was Medicaid, with the majority of Commercial volumes flowing through the top 6 pharmacy benefit managers (PBMs) (source: SHS PHAST: 2018). Taken together and based on 2018 utilization data, potential volume of approximately 1.2 billion tablets would be addressable by AG-APADAZ among those PBMs alone. Currently, APADAZ and AG-APADAZ are not yet covered by Medicare, although formulary review is in progress and expected to be completed within 90 days.

“Widespread formulary adoption for AG-APADAZ has advanced much faster than we anticipated, though there remains work to be done to gain an advantage over currently available generic HC/APAP products. We believe this milestone indicates that KemPharm’s strategy of offering an authorized generic of APADAZ at prices comparable to generic HC/APAP may be an attractive proposition. We continue to believe that the replacement of current HC/APAP products with APADAZ and its authorized generic will be a meaningful market opportunity based on this achievement and prior discussions with payors,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “APADAZ and its authorized generic remain on track for commercial launch in the second half of 2019.”

Conference Call Information:

KemPharm will host a brief conference call and live audio webcast with slide presentation today, Wednesday, March 13, 2019, at 8:30 a.m. ET. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 8690988

An audio webcast with slide presentation will be accessible via the Investor Relations section of the KemPharm website www.investors.kempharm.com. An archive of the webcast and presentation will remain available for 90 days beginning later today, March 13, 2019, at approximately 9:30 a.m. ET.

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.

APADAZ®

APADAZ® was developed from KemPharm's proprietary LAT™ (Ligand Activated Therapy) platform technology and is intended for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. APADAZ is differentiated from other prescription opioids as it is the first FDA-approved product to contain a prodrug of hydrocodone. A prodrug is chemically inert, or inactive, on its own. When ingested, enzymes in the gastrointestinal tract cleave the ligand from the prodrug (benzhydrocodone) and release the parent drug (hydrocodone), which can then exert its therapeutic effect. The final approved product labeling for APADAZ includes these and other data points but concludes that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

The approval of APADAZ via the 505(b)(2) pathway was based in part on pharmacokinetic studies with Vicoprofen®, Ultracet®, and Norco® in which APADAZ demonstrated exposure to hydrocodone and acetaminophen (APAP) that is expected to result in therapeutic effects equivalent to currently approved immediate-release hydrocodone/APAP combination products when administered orally as intended.

Indication:
APADAZ® contains an opioid agonist and acetaminophen and is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use:
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve APADAZ® for use in patients for whom alternative treatment options [e.g., non-opioid analgesics] have not been or are not expected tolerated, or have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Important Safety Information:

APADAZ® is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity to hydrocodone or acetaminophen.

APADAZ® contains benzhydrocodone, a Schedule II controlled substance. APADAZ® can be abused and is subject to misuse, addiction, and criminal diversion.

Potential risks associated with APADAZ® include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 CYP3A4 inhibitors and inducers, acetaminophen hepatoxicity risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants, risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, serious skin reactions, risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness, hypersensitivity/anaphylaxis, risks of use in patients with gastrointestinal conditions, risk of use in patients with seizure disorders, and withdrawal, risks of driving and operating machinery.

Potential drug interactions with APADAZ® include:

- Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue APADAZ® if serotonin syndrome is suspected.
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with APADAZ® because they may reduce analgesic effect of APADAZ® or precipitate withdrawal symptoms.
- Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydrocodone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.

Most common adverse reactions (>5%) are nausea, somnolence, vomiting, constipation, pruritus, dizziness, and headache.

The Full Prescribing Information for APADAZ® contains the following Boxed Warning:

WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; HEPATOTOXICITY; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse:

APADAZ® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing APADAZ® and monitor all patients regularly for the development of these behaviors and conditions.

Risk Evaluation and Mitigation Strategy (REMS):

To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to

- complete a REMS-compliant education program,
- counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products,
- emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and
- consider other tools to improve patient, household, and community safety.

Life-Threatening Respiratory Depression:

Serious, life-threatening, or fatal respiratory depression may occur with use of APADAZ®. Monitor for respiratory depression, especially during initiation of APADAZ® or following a dose increase.

Accidental Ingestion:

Accidental ingestion of even one dose of APADAZ®, especially by children, can result in a fatal overdose of hydrocodone.

Neonatal Opioid Withdrawal Syndrome:

Prolonged use of APADAZ® during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction:

The concomitant use of APADAZ® with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving APADAZ® and any CYP3A4 inhibitor or inducer.

Hepatotoxicity:

APADAZ® contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants:

Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of APADAZ® and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

For Important Safety Information including full prescribing information, visit: www.kempharm.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 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 estimate of the addressable market and launch timeline for APADAZ, 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 / Joshua Drumm, Ph.D.
Tiberend Strategic Advisors, Inc.
212-375-2665 / 2664
jrando@tiberend.com
jdrumm@tiberend.com

Exhibit 99.2

KemPharm

APADAZ® Commercial Update Call

March 13, 2019

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about 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 Annual Report on Form 10-K filed with the SEC on March 1, 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.

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

Key Highlights

- According to estimates by Managed Markets Insights and Technologies (MMIT), branded APADAZ® has 15% unrestricted formulary access to all commercial lives
- Authorized generic (benzhydrocodone/APAP, or "AG-APADAZ") has 91% unrestricted access to all commercial lives and 90% unrestricted access to all state Medicaid lives
- We believe these data support broad initial coverage for AG-APADAZ
  - AG-APADAZ in preferred generic position on majority of plans
  - Based on several publicly-available clinical evaluations, some plans appear to be receptive to potential differentiation of APADAZ

Source: Managed Markets Insights and Technology; www.formularylookup.com

HC/APAP Market Update - 2018

- Large volume, primarily generic market in 2018
- Hydrocodone/acetaminophen (HC/APAP) coverage primarily driven by Commercial and Medicare coverage

Payor Category	2018 Utilization (HC/APAP tabs)	% of Total
Commercial	1,625,304,292	41%
Medicare	1,569,498,241	39%
Managed Medicaid	351,642,426	9%
Assistance Programs	160,499,083	4%
Cash	156,152,543	4%
Medicaid	129,834,982	3%
Total	3,992,931,567	100%

Source: SHS PHAST: 2018

HC/APAP Market Update - 2018

- Most HC/APAP volume flows through the top 6 PBM's

Utilization Volume by PBM (Top 6)

PBM	2018 Utilization (HC/APAP tabs)
Express Scripts	412,716,705
CVS Caremark	368,923,972
OptumRx	237,666,117
Prime Therapeutics	143,341,764
MedImpact Healthcare	52,234,276
Cigna	41,026,605
Total	1,225,909,439

Sources: SHS PHAST: 2018

APADAZ® Formulary Coverage - Commercial

- According to MMIT estimates, branded APADAZ has 15% unrestricted access for Commercial plans, generally at a Tier 3 or equivalent status
- According to MMIT estimates, AG-APADAZ has 91% unrestricted access for Commercial plans
  - Listed at preferred generic for 78% of plans
  - Only 4% of plans indicate no coverage at this time
- We believe the first major step for wide formulary adoption with Commercial plans has been achieved
  - Fewer barriers to plan preference for AG-APADAZ over current HC/APAP
  - Few barriers to broad script reimbursement if plans start shifting utilization to AG-APADAZ

Source: Managed Markets Insights and Technology; www.formularylookup.com

APADAZ® Formulary Coverage - State Medicaids

- According to MMIT estimates, AG-APADAZ has unrestricted access to 90% of state Medicaid plans with 59% in the preferred generic category
- While smaller overall compared to Commercial and Medicare lives, we believe state Medicaids may represent a lower barrier to preferred adoption of AG-APADAZ
- According to MMIT data, some state Medicaid plans have placed AG-APADAZ as a preferred generic, while requiring a prior authorization (PA) for HC/APAP
- States also have the power to remove products from their formularies completely

Source: Managed Markets Insights and Technology; www.formularylookup.com

APADAZ® Next Steps

- We believe broad formulary adoption with preferred generic status represents a key milestone to begin market conversion
- Actively working with plans to "prefer" AG-APADAZ over HC/APAP
- Outreach to current and previous PBM/payor leads (now on formulary with preferred generic status) by KVK and the managed care access team; remain on track for 2H 2019 launch
- KVK is concentrating its planning efforts on manufacturing and distribution for smaller, pilot-scale launches initially, followed by potential national stocking to support broad formulary access
- Based on current formulary access and 2018 utilization data, potential volume of more than 2B tabs addressable for AG-APADAZ
    - Medicare formulary evaluation underway