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 21, 2022

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 Instruction 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	The Nasdaq Stock Market LLC (Nasdaq Global Select 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 March 21, 2022, KemPharm, Inc., a Delaware corporation (the “Company”), issued a press release (the “Press Release”) announcing that the Company had completed its analysis of the full data set from its Phase 1 clinical trial exploring the safety and pharmacokinetics ("PK") of serdexmethylphenidate ("SDX") delivered at doses higher than those previously studied. A copy of the Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 21, 2022, the Company announced that it had completed its analysis of the full data set from its Phase 1 clinical trial exploring the safety and PK of SDX delivered at doses higher than those previously studied. SDX, the Company’s proprietary prodrug of d-methylphenidate ("d-MPH"), is the sole active pharmaceutical ingredient in KP1077, which the Company is developing as a treatment for idiopathic hypersomnia ("IH").

The full data set, which builds upon top-line data previously reported on December 14, 2021, affirmed that 240 mg and 360 mg doses of SDX were well-tolerated and produced d-MPH exposure that appeared to increase proportionally with dose. Mean d-MPH plasma concentrations demonstrated a gradual increase after SDX administration, reaching a broad peak from eight to twelve hours post-dose, followed by a shallow decline thereafter. Increased wakefulness, alertness, hypervigilance, and insomnia effects were reported by study participants, which suggests that SDX produced targeted pharmacodynamic effects that could benefit patients with IH and other sleep disorders.

The Higher-Dose SDX Phase 1 clinical trial was a dose-escalation study to determine the PK, pharmacodynamic stimulant effects, and safety of single oral doses of SDX in subjects with a history of high-dose stimulant use. Following screening, subjects were treated with single, ascending doses of SDX (240, 360, 480, and 600 mg), with each dose separated by a minimum of 14 days. A total of 14 subjects received at least one dose of SDX with 14, 10, 7 and 2 subjects dosed with 240, 360, 480, and 600 mg, respectively.

Subject-rated pharmacodynamic effects of Drowsiness/Alertness and Energized were scored on a Visual Analogue Scale (VAS) at several timepoints post-dose. The results indicate that the VAS scores for Drowsiness/Alertness (bipolar scale: 0 to 100) increased with dose with maximum effects in the early to late afternoon, with the most pronounced effects measured at the two highest doses. Similarly, mean VAS scores of feeling Energized (unipolar scale: 0 to 100) increased from mean baseline scores of less than 20 and up to a peak range of 61 to 82, across all dose levels, with the largest effects measured at the two highest doses. Both Alertness and feeling Energized are relevant pharmacodynamic metrics for treating patients with sleep disorders like IH.

The Company also provided an update on several important upcoming milestones for the KP1077 development program. The Company anticipates filing an Investigational New Drug application for KP1077 as early as the second quarter of 2022 and subsequently initiating a Phase 2 trial in patients with IH in the second half of 2022. Additionally, we expect to receive results from an additional trial to assess the relative cardiovascular safety of SDX vs. current stimulant treatments also in the second half of 2022.

This Form 8-K contains 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, including the continued commercialization of AZSTARYS and the further development of the Company’s pipeline of product candidates, or the suitability of SDX for any specific disease indication, are based on information currently available to the Company and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning the Company’s business are described in detail in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and the Company’s other filings with the Securities and Exchange Commission. The Company 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.

Item 9.01 Financial Statements and Exhibits.

The following exhibits relating to Items 7.01 and 8.01 shall be deemed to be furnished, and not filed:

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 21, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

KemPharm, Inc.

Date: March 21, 2022

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

KemPharm Announces Full Data Set from Higher-Dose Serdexmethylphenidate (SDX) Phase 1 Clinical Trial

Data demonstrate higher doses of SDX were generally well-tolerated and produced targeted pharmacodynamic effects that may be beneficial for the treatment of idiopathic hypersomnia (IH) and other sleep disorders

Upcoming anticipated development milestones for KP1077 include: IND filing as early as Q2 2022; Phase 2 trial initiation in IH patients and announce results of study to examine safety related to cardiovascular effects expected in 2H 2022

Celebration, FL – March 21, 2022 – KemPharm, Inc. (NasdaqGS: KMPH)(the Company, or KemPharm), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced that the Company has completed its analysis of the full data set from its Phase 1 clinical trial exploring the safety and pharmacokinetics (PK) of serdexmethylphenidate (SDX) delivered at doses higher than those previously studied. SDX, KemPharm's proprietary prodrug of d-methylphenidate (d-MPH), is the sole active pharmaceutical ingredient (API) in KP1077, which KemPharm is developing as a treatment for idiopathic hypersomnia (IH).

The full data set, which builds upon top-line data previously reported on December 14, 2021, affirmed that 240 mg and 360 mg doses of SDX were well-tolerated and produced d-MPH exposure that appeared to increase proportionally with dose. Mean d-MPH plasma concentrations demonstrated a gradual increase after SDX administration, reaching a broad peak from eight to twelve hours post-dose, followed by a shallow decline thereafter. Increased wakefulness, alertness, hypervigilance, and insomnia effects were reported by study participants, which suggests that SDX produced targeted pharmacodynamic effects that could benefit patients with IH and other sleep disorders.

"The full data set from the Phase 1 clinical trial of 'higher-dose' SDX affirms our decision to select KP1077 as a treatment for IH as our lead development candidate and informs further development of SDX in related disorders," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "IH is a rare neurological sleep disorder characterized by excessive daytime sleepiness, extreme difficulty waking, and severe brain fog, despite adequate or even prolonged nighttime sleep. Unfortunately, the treatment options currently available only address a limited range of these symptoms and are known to cause adverse events. The data generated in the Phase 1 trial of higher-dose SDX suggest that KP1077 is well-tolerated and possesses unique properties that could potentially address excessive daytime sleepiness as well as other debilitating symptoms associated with IH."

KemPharm also provided an update on several important upcoming milestones for the KP1077 development program. The Company anticipates filing an Investigational New Drug (IND) application for KP1077 as early as the second quarter of 2022 and subsequently initiating a Phase 2 trial in patients with IH in the second half of 2022. Additionally, we expect to receive results from an additional trial to assess the relative cardiovascular safety of SDX vs. current stimulant treatments also in the second half of 2022.

About the Higher-Dose SDX Phase 1 Clinical Trial:

The Higher-Dose SDX Phase 1 clinical trial was a dose-escalation study to determine the PK, pharmacodynamic stimulant effects, and safety of single oral doses of SDX in subjects with a history of high-dose stimulant use. Following screening, subjects were treated with single, ascending doses of SDX (240, 360, 480, and 600 mg), with each dose separated by a minimum of 14 days. A total of 14 subjects received at least one dose of SDX with 14, 10, 7 and 2 subjects dosed with 240, 360, 480, and 600 mg, respectively.

Subject-rated pharmacodynamic effects of Drowsiness/Alertness and Energized were scored on a Visual Analogue Scale (VAS) at several timepoints post-dose. The results indicate that the VAS scores for Drowsiness/Alertness (bipolar scale: 0 to 100) increased with dose with maximum effects in the early to late afternoon, with the most pronounced effects measured at the two highest doses. Similarly, mean VAS scores of feeling Energized (unipolar scale: 0 to 100) increased from mean baseline scores of less than 20 and up to a peak range of 61 to 82, across all dose levels, with the largest effects measured at the two highest doses. Both Alertness and feeling Energized are relevant pharmacodynamic metrics for treating patients with sleep disorders like IH.

The following table summarizes the trial results for the relevant pharmacodynamic metrics:

Drowsiness/Alertness VAS[1]	(bipolar scale: 0 to 100)
Baseline Score Range:	37 to 50
Peak Score Range:	67 to 89

Energized VAS[2]	(unipolar scale: 0 to 100)
Baseline Score Range:	15 to 20
Peak Score Range:	61 to 82

[1] The Drowsiness/Alertness VAS is an at-the-moment bipolar scale where a score of 50 is neither drowsy nor alert, a score below 50 is drowsy, and a score above 50 is alert.
[2] The Energized VAS is an at-the-moment unipolar scale measuring the feeling of excess energy where a score of 0 is "definitely no" and a score of 100 is "definitely so"

The full data and detailed results are expected to be submitted for presentation at future scientific conferences and publication in peer-reviewed journals.

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) platform technology. KemPharm utilizes its proprietary LAT® platform 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 idiopathic hypersomnia (IH) and other CNS/rare diseases. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a new once-daily treatment for ADHD in patents age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S., and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S. 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation and which can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "could," "intend," "target," "predict," or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding the potential benefits of KP1077, the promise and potential impact of our preclinical or clinical trial data, including without limitation the timing and results of any clinical trials or readouts, the timing or results of any IND applications, the potential benefits of KP1077, SDX or any other product candidates for any specific disease indication, or the potential benefits of any of KemPharm's product candidates, the submission of data for publication at scientific conferences or publication in journals, and our strategic and product development objectives. 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 known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2020, KemPharm's Quarterly Report for the quarter ended September 30, 2021, and KemPharm's other filings with the Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

This press release also may contain 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.

KemPharm Contacts:

Tiberend Strategic Advisors, Inc.
Jason Rando/Daniel Kontoh-Boateng
(212) 375-2665 / 2664
jrando@tiberend.com
dboateng@tiberend.com