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): December 14, 2021

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	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 December 14, 2021, KemPharm, Inc., a Delaware corporation (the "Company"), issued a press release (the "Press Release") announcing top-line results from its clinical trial exploring the safety and pharmacokinetics of serdexmethylphenidate delivered at doses higher than those studied as part of the AZSTARYS development program. 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 December 14, 2021, the Company announced top-line results from its clinical trial exploring the safety and pharmacokinetics ("PK") of serdexmethylphenidate ("SDX") delivered at doses higher than those studied as part of the AZSTARYS development program. AZSTARYS is a once-daily product approved for the treatment of attention deficit hyperactivity disorder in patients ages six years and older which is being commercialized in the U.S. by Corium, Inc., a portfolio company of Gurnet Point Capital. SDX is KemPharm's proprietary prodrug of d-methylphenidate ("d-MPH") and the primary active pharmaceutical ingredient in AZSTARYS. The U.S. Drug Enforcement Agency has classified SDX as a Schedule IV controlled substance, which is a lower schedule than all other currently available methylphenidate-based products.

The dose-ascending Phase 1 clinical trial enrolled 14 subjects who were administered up to four increasing single oral doses of SDX, each at least 14 days apart. Doses ranged from 240 mg to 600 mg, with the number of individual subjects receiving more than one dose of SDX varied with 10, 7 and 2 subjects receiving 360 mg, 480 mg and 600 mg, respectively. Doses greater than 240 mg were above those studied under the AZSTARYS development program. Data from the study indicated that the 240 mg and 360 mg doses of SDX were well-tolerated and produced d-MPH exposure generally proportional to the dose. Consistent with previous studies, after dosing d-MPH plasma concentrations demonstrated a gradual increase followed by a slow decline resulting in prototypical broad d-MPH exposure peak observed after oral administration of SDX. Additionally, data suggested that the higher SDX doses produced targeted biological effects that potentially align with the treatment of idiopathic hypersomnia ("IH") and other sleep disorders, as well as stimulant use disorder ("SUD"). Specifically, increased wakefulness, alertness, excitability and insomnia effects were observed in the study. Modest increases in Drug Liking, which was expected given the SDX's status as a Schedule IV controlled substance, coupled with the stable PK profile predicted at "steady-state" are factors thought to be predictive of a potentially successful maintenance therapy for SUD and related disorders.

Based on these results, the Company is assessing the development programs, approval pathways and commercial potential of two product candidates based on SDX, KP1077 for the treatment of IH, and KP879 for the treatment of SUD, and expects to provide an update on its plans to expand its pipeline early in the first quarter of 2022. The Company is also exploring other disease indications that may benefit from SDX-based treatments.

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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled "KemPharm, Inc. Announces Top-Line Results from Clinical Trial Evaluating the Safety and Pharmacokinetics of "Higher-Dose SDX"" dated December 14, 2021.
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 thereunto duly authorized.

KemPharm, Inc.

Date: December 14, 2021

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

Exhibit 99.1

KemPharm, Inc. Announces Top-Line Results from Clinical Trial Evaluating the Safety and Pharmacokinetics of "Higher-Dose SDX"

Data reveal serdexmethylphenidate (SDX) delivered at doses higher than those studied with AZSTARYS® is well-tolerated, yields dose-proportional d-MPH exposure, and produces targeted biological effects

Celebration, FL – December 14, 2021 – KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, announced today top-line results from its clinical trial exploring the safety and pharmacokinetics of serdexmethylphenidate (SDX) delivered at doses higher than those studied as part of the AZSTARYS® development program. AZSTARYS is a once-daily product approved for the treatment of attention deficit hyperactivity disorder (ADHD) in patients ages six years and older which is being commercialized in the U.S. by Corium, Inc., a portfolio company of Gurnet Point Capital (GPC). SDX is KemPharm's proprietary prodrug of d-methylphenidate (d-MPH) and the primary active pharmaceutical ingredient in AZSTARYS. The U.S. Drug Enforcement Agency (DEA) has classified SDX as a Schedule IV controlled substance, which is a lower schedule than all other currently available methylphenidate-based products.

The dose-ascending Phase 1 clinical trial enrolled 14 subjects who were administered up to four increasing single oral doses of SDX, each at least 14 days apart. Doses ranged from 240 mg to 600 mg. Of those individual subjects administered more than one dose of SDX, 10 received 360 mg, seven received 480 mg, and two received 600 mg. Doses greater than 240 mg were above those studied under the AZSTARYS development program. Data from the study indicated that the 240 mg and 360 mg doses of SDX were well-tolerated and produced d-MPH exposure generally proportional to the dose. Consistent with previous studies, after dosing d-MPH plasma concentrations demonstrated a gradual increase followed by a slow decline resulting in prototypical broad d-MPH exposure peak observed after oral administration of SDX. Additionally, data suggested that the higher SDX doses produced targeted biological effects that potentially align with the treatment of idiopathic hypersomnia (IH) and other sleep disorders, as well as stimulant use disorder (SUD). Specifically, increased wakefulness, alertness, excitability and insomnia effects were observed in the study. Modest increases in Drug Liking, which was expected given the SDX's status as a Schedule IV controlled substance, coupled with the stable PK profile predicted at "steady-state," are factors thought to be predictive of a potentially successful maintenance therapy for SUD and related disorders.

Based on these results, KemPharm is assessing the development programs, approval pathways and commercial potential of two product candidates based on SDX, KP1077 for the treatment of IH, and KP879 for the treatment of SUD, and expects to provide an update on its plans to expand its pipeline in early Q1 2022. KemPharm is also exploring other disease indications that may benefit from SDX-based treatments.

"The intent of this clinical trial was to determine if higher doses of SDX could be administered safely and produce biological effects consistent with the dosing and in alignment with disease indications that we believe could benefit from the unique properties of SDX. In short, the results were exactly what we were hoping to achieve, and we now expect to finalize our SDX development plan and commercial value assessment in early 2022," said Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "We believe the status of SDX as a Schedule IV controlled substance, combined with the unique pharmacokinetic profile of SDX, offers multiple treatment opportunities in a variety of disease indications, which has the potential to be the basis for a portfolio of SDX-based products."

About AZSTARYS®:

AZSTARYS is an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years or older. AZSTARYS consists of SDX, KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH. Corium, Inc., a portfolio company of Gurnet Point Capital, is leading all commercialization efforts for AZSTARYS in the U.S.

The complete approved prescribing information for AZSTARYS may be downloaded in PDF format here:
https://kempharm.com/wp-content/uploads/2021/03/AZSTARYS-Master-Label-Final_20210302.pdf

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, stimulant use disorder (SUD) and CNS rare diseases, including idiopathic hypersomnia (IH). 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), and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's 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, including the continued commercialization of AZSTARYS® and the further development of KemPharm's pipeline of product candidates, or the suitability of SDX for any specific disease indication, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and KemPharm's other filings 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:

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