

**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 3, 2021 (March 2, 2021)

KemPharm, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer Identification No.)

1180 Celebration Boulevard, Suite 103, Celebration, FL
(Address of Principal Executive Offices)

34747
(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

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 2, 2021, KemPharm, Inc., or the Company, issued a press release announcing that the U.S. Food and Drug Administration, or the FDA, approved the New Drug Application, or NDA, for AZSTARYS™ (serdexmethylphenidate and dexamethylphenidate capsules, for oral use, CII), formerly referred to as KP415, a once-daily product for the treatment of attention deficit hyperactivity disorder, or ADHD in patients age six years and older. The Company will conduct a conference call and live audit webcast with slide presentation today, Wednesday, March 3, 2021, at 8:30 a.m. ET.

A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The information contained in this Item 7.01, the press release furnished as Exhibit 99.1 and the presentation furnished as Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are 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 8.01 Other Events.

On March 2, 2021, the Company announced that the FDA approved the NDA for AZSTARYS™ (serdexmethylphenidate and dexamethylphenidate capsules, for oral use, CII), formerly referred to as KP415, a once-daily product for the treatment of ADHD in patients age six years and older.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Announces FDA Approval of AZSTARYS™ (serdexmethylphenidate and dexamethylphenidate capsules, for oral use, CII), A New Once-Daily Treatment for ADHD” dated March 2, 2021.
99.2	Presentation titled "AZSTARYS™ FDA Approval" dated March 3, 2021.

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 3, 2021

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



KemPharm Announces FDA Approval of AZSTARYS™ (serdexmethylphenidate and dexamethylphenidate capsules, for oral use, CII), A New Once-Daily Treatment for ADHD

Conference Call and Live Audio Webcast Scheduled for Tomorrow, Wednesday, March 3, at 8:30 a.m. ET

Celebration, FL – March 2, 2021 – KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application for (NDA) AZSTARYS™ (formerly referred to as KP415), a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older. AZSTARYS consists of serdexmethylphenidate (SDX), KemPharm’s prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH.

Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital (GPC), will lead the commercialization of AZSTARYS per the definitive collaboration and license agreement (the “License Agreement”) between KemPharm and an affiliate of GPC. Corium expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

“The FDA approval of the AZSTARYS NDA is a transformational event for KemPharm and, we believe, an important advancement in the treatment of ADHD,” said Travis C. Mickle, Ph.D., President and CEO of KemPharm. “Today’s approval highlights both the value potential of SDX, our prodrug of d-MPH, and the ability of our LAT® platform technology to develop new prodrugs of approved medications that improve one or more of the attributes of the parent drug. We look forward to continuing our support of Corium as they forge ahead with the commercial launch of AZSTARYS.”

“Today’s approval by the FDA is met with great excitement for this innovative new ADHD therapy and the potential it holds to meet the unmet needs of children, adolescents and adults,” said Perry Sternberg, CEO of Corium. “Our team is mobilized to put our commercial plans into action as the approval of the AZSTARYS NDA now enables us to finalize our preparations for commercial launch as early as the second half of this year.”

Ann Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine and an investigator in the AZSTARYS clinical trial, commented: “The ADHD industry, and specifically the MPH space, has seen little innovation in recent years, leaving prescribers and patients desiring new treatment options. In my research and practice, three properties are repeatedly cited by patients and their caregivers as being underserved by current ADHD medications: onset of action, duration of effect and consistency of therapy. Having investigated AZSTARYS and directly observed its clinical impact on patients, I believe this product will be an important new tool for physicians to use in providing effective care for patients with ADHD.”

As a result of the FDA's approval of the AZSTARYS NDA, KemPharm has earned a regulatory milestone payment following FDA approval as provided under the License Agreement, and KemPharm is working with GPC to evaluate the related provisions and amounts. Under the License Agreement, KemPharm may be eligible for up to \$468 million in regulatory and sales milestone payments, as well as tiered royalty payments, on a product-by-product basis for net sales, with potential percentages up to the mid-twenties for U.S. net sales, and up to the mid-single digits of net sales in each country outside of the U.S.

The complete label for AZSTARYS, including prescribing information and important safety information, may be found at www.kempharm.com/pipeline-products/#kp415.

The complete label may also be downloaded in PDF format here:

<http://ml.globenewswire.com/Resource/Download/4f63af91-9427-40da-b881-82a5e22a0315>

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation tomorrow, Wednesday, March 3, 2021, at 8:30 a.m. ET, to discuss FDA approval of the AZSTARYS NDA. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 4272912

An audio webcast with slide presentation will be accessible via the Investor Relations section of the Company's website, <http://investors.kempharm.com/>. An archive of the webcast and presentation will be available for 90 days beginning tomorrow, March 3, 2021, at approximately 9:30 a.m. ET.

About Attention Deficit Hyperactivity Disorder (ADHD):

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common mental disorders affecting children. ADHD also affects many adults. Symptoms of ADHD include inattention (not being able to keep focus), hyperactivity (excess movement that is not fitting to the setting) and impulsivity (hasty acts that occur in the moment without thought).¹ An estimated 8.4% of children and 2.5% of adults have ADHD.^{2,3}

The ADHD market accounted for approximately \$17.9 billion of revenue in 2019 with a year-over-year prescription growth rate greater than four percent (4%). Within this, the branded portion of the ADHD market was approximately \$7.4 billion in 2019, with extended-release products representing more than 97% of the branded prescriptions. In 2019, the methylphenidate segment of the ADHD market accounted for approximately 20 million prescriptions and \$4.9 billion in sales.

¹ American Psychiatric Association (<https://www.psychiatry.org/patients-families/adhd/what-is-adhd>)

² Danielson, ML, et al. [Prevalence of Parent-Reported ADHD Diagnosis and Associated Treatment Among U.S. Children and Adolescents, 2016](#). Journal of Clinical Child & Adolescent Psychology, Volume 47, 2018 - Issue 2

³ Simon V , Czobor P, Bálint S , et al: [Prevalence and correlates of adult attention-deficit hyperactivity disorder: a meta-analysis](#). Br J Psychiatry 194(3):204–211, 2009

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.

The complete approved prescribing information for AZSTARYS may be downloaded in PDF format here: <http://ml.globenewswire.com/Resource/Download/4f63af91-9427-40da-b881-82a5e22a0315>

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 product portfolio is highlighted by AZSTARYS™, an FDA-approved, once-daily treatment for attention deficit hyperactivity disorder (ADHD) which is based on serdexmethylphenidate, (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH). KemPharm is also advancing several clinical development candidates, including KP484 for the treatment of ADHD and KP879 for the treatment of Stimulant Use Disorder (SUD). AZSTARYS, KP484, and KP879 are all based on SDX. 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 KemPharm's 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 include statements about the commercial launch of AZSTARYS, including the timing of launch, the regulatory milestone payment, and the potential clinical benefits of AZSTARYS. 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 the "Risk Factors" sections of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, KemPharm's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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.

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KemPharm

AZSTARYS™ FDA Approval

March 3, 2021

Trademarks referenced herein are held by their respective owners.

Cautionary Note Regarding Presentation Information

This presentation 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 KemPharm's 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 statements about the commercial launch of AZSTARYS, including the timing of launch, the regulatory milestone payment, and the potential clinical benefits of AZSTARYS. 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 the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, KemPharm's Quarterly Report for the quarter ended September 30, 2020, 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.

This presentation 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.



ASTARYS™ Approval

- ✓ **Announced FDA Approval of AZSTARYS (serdexmethylphenidate and dexamethylphenidate capsules, for oral use, CII) A New Once-Daily Treatment for ADHD**
 - Consists of serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH
 - Corium expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021

- ✓ **AZSTARYS NDA Approval is a Significant Milestone for KemPharm**
 - Demonstrates value potential of SDX and KemPharm's groundbreaking LAT® platform
 - Eligible to receive up to \$468 million in regulatory and sales milestone payments, and tiered royalty payments per our License Agreement with an affiliate of GPC



AZSTARYS™ Label

Sections 1 and 2.3

Section 1: Indications and Usage

- AZSTARYS is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

Section 2.3: Administration Information

- Administer AZSTARYS orally once daily in the morning with or without food.
- AZSTARYS capsules may be taken whole, or opened and the entire contents sprinkled into 50 mL of water or over 2 tablespoons of applesauce.

IMPORTANT SAFETY INFORMATION, Contraindications, Warnings and Precautions, Adverse Reactions and Drug Interactions may be found within the full Prescribing Information at www.kempharm.com/pipeline-products/#kp415



Section 6.1: Clinical Trials Experience

To adjust for normal growth, z-scores were derived (measured in standard deviations [SD]); z- scores normalize for the natural growth of children and adolescents by comparisons to age- and sex-matched population standards. A z-score change less than 0.5 SD is considered not clinically significant.

In this study, the mean increase in weight from baseline to Month 12 was 3.4 kg among study completers. The mean change in z-score from baseline to Month 12 was -0.20, indicating a lower than expected increase in body weight compared to children of the same age and sex, on average. Most of the weight z-score decline occurred in the first 4 months of treatment.

The mean increase in height from baseline to Month 12 was 4.9 cm among completers. Using the same z-score analysis for height, the mean change in z-score from baseline to Month 12 was -0.21, indicating a lower than expected increase in height compared to pediatric patients of the same age and sex, on average.

IMPORTANT SAFETY INFORMATION, Contraindications, Warnings and Precautions, Adverse Reactions and Drug Interactions may be found within the full Prescribing Information at www.kempharm.com/pipeline-products/#kp415



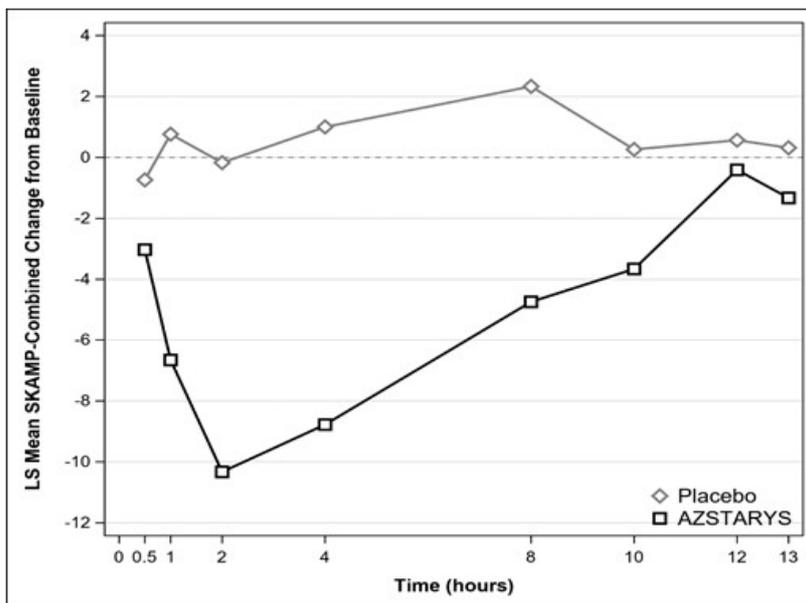
Section 12.3: Pharmacokinetics

- No clinically meaningful differences in the exposure of dexamethylphenidate were observed when administered after an overnight fast, with a high-fat, high-caloric meal, or sprinkled onto applesauce or water. The median time to peak plasma concentration (T_{max}) was lengthened from 2 to 4-4.5 hours in the presence of food.
- Serdexamethylphenidate is a prodrug of dexamethylphenidate and is likely converted to dexamethylphenidate mainly in the lower gastrointestinal tract.

IMPORTANT SAFETY INFORMATION, Contraindications, Warnings and Precautions, Adverse Reactions and Drug Interactions may be found within the full Prescribing Information at www.kempharm.com/pipeline-products/#kp415



Figure 2: LS Mean Change in SKAMP-Combined Score from Baseline after Treatment with AZSTARYS or Placebo during Classroom Day in Pediatric Patients (6 to 12 years) with ADHD



IMPORTANT SAFETY INFORMATION, Contraindications, Warnings and Precautions, Adverse Reactions and Drug Interactions may be found within the full Prescribing Information at www.kempharm.com/pipeline-products/#kp415



Partnership with Gurnet Point Capital and Corium, Inc.

- Worldwide license with an affiliate of Gurnet Point Capital (GPC) announced Sept 2019
 - Corium, a GPC portfolio company, is leading all commercialization activities
- License agreement includes a total of up to \$483 million in upfront and milestone payments for KP415, as well as tiered royalties on net sales
 - Received \$10 million at signing, \$5 million at KP415 NDA acceptance
 - Now eligible for up to \$468 million in regulatory and sales milestone payments related to AZSTARYS™
- Corium is led by Perry Sternberg, President and CEO, as well as many other executives with prior experience at Shire
 - Corium finalizing preparations for commercial launch as early as the second half of 2021
 - Manufacturing validation underway



KemPharm: Next Steps and Outlook

AZSTARYS™ <ul style="list-style-type: none">- FDA has approved AZSTARYS NDA- KP415 eligible to receive up to \$468 million in regulatory and sales milestone payments- Tiered royalties as a percentage of U.S. net sales ranging from the high-single digits to mid-twenties	Improved Financial Position <ul style="list-style-type: none">- Multi-phase financial restructure process completed- Debt and balance sheet issues addressed- KMPH stock relisted on Nasdaq effective Jan 8, 2021- Project cash burn remains at ~\$1M/quarter
AZSTARYS Commercial Progress <ul style="list-style-type: none">- Corium expects to make AZSTARYS commercially available in the U.S. as early as 2H 2021- KemPharm working with Corium on commercial supply for anticipated 2H 2021 launch	Beyond KP415 <ul style="list-style-type: none">- Expanded services agreement with Corium adds additional revenue- KP879 IND cleared by FDA; initiation of clinical trial program expected by mid-2021- KVK-Tech/Sure Med collaboration for APADAZ, Perspectives in Care program launched in Alabama in Dec 2020





KemPharm

AZSTARYS™ FDA Approval

March 3, 2021