

**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): April 8, 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 1.01 Entry into a Material Definitive Agreement.

On April 8, 2021, KemPharm, Inc. (the “Company”) entered into Amendment No. 1 (the “Amendment”) to that certain Collaboration and License Agreement, dated September 3, 2019, by and between the Company and Commave Therapeutics SA (formerly known as Boston Pharmaceuticals Holdings SA) (“Commave”) (as amended, the “License Agreement”). As previously disclosed, under the License Agreement, the Company has granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize its product candidates containing SDX and d-MPH, including AZSTARYS™ and KP484.

Pursuant to the Amendment, the parties agreed to modify the compensation terms of the License Agreement. Commave has previously paid the Company an upfront payment of \$10 million upon entry into the original License Agreement and \$5 million upon the FDA acceptance of the NDA submission for AZSTARYS. Pursuant to the Amendment, Commave has agreed to pay the Company \$10.0 million within five calendar days of the effective date of the Amendment as a result of the regulatory approval of AZSTARYS in the United States. Commave will also pay the Company \$10 million within thirty calendar days following receipt of the scheduling determination of the compound serdexmethylphenidate, or SDX, by the U.S. Drug Enforcement Administration. SDX is the prodrug component of AZSTARYS. In addition, the Amendment increases the total remaining future regulatory and sales milestone payments related to AZSTARYS to up to an aggregate of \$590 million in payments upon the occurrence of specified regulatory milestones related to AZSTARYS and upon the achievement of specified U.S. net sales milestones. Further, Commave has agreed to pay the Company quarterly, tiered royalty payments ranging from a percentage in the high single digits to the mid-twenties of Net Sales (as defined in the KP415 License Agreement) in the United States and a percentage in the low to mid-single digits of Net Sales in each country outside the United States, in each case subject to specified reductions under certain conditions, including with respect to the final approval label, as described in the License Agreement. Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the Royalty Term (as defined in the License Agreement) for the applicable product.

Pursuant to the Amendment, the parties also agreed to modify Commave’s right of first refusal such that KemPharm’s product candidate, KP922, is no longer subject to Commave’s right of first refusal to acquire, license or commercialize any Additional Product Candidate. Commave’s right of first refusal shall only apply to any Additional Product Candidate which contains SDX, with such right of first refusal expiring upon the acceptance of a new drug application for such Additional Product Candidate containing SDX.

Except as modified by the Amendment, all terms and conditions of the License Agreement remain in full force and effect.

The foregoing is a summary description of certain terms of the Amendment, is not complete and is qualified in its entirety by reference to the text of the Amendment, which the Company expects to file as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending June 30, 2021.

Item 7.01 Regulation FD Disclosure.

On April 8, 2021, the Company issued a press release to announce the entry into the Amendment, as well as information regarding a conference call and live audio webcast with a slide presentation related thereto. A copy of the press release and presentation are furnished as Exhibits 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 Exchange Act and are not incorporated by reference into any of the Company’s filings under 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.

Caution Concerning Forward Looking Statements:

This Current Report on Form 8-K 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 the Company's potential receipt of milestone and royalty payments pursuant to the License Agreement, 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 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 "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020, 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, dated April 8, 2021.
99.2	Management Presentation, dated April 8, 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: April 8, 2021

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



KemPharm Announces Amendment to Licensing Agreement with Gurnet Point Capital Affiliate Following FDA Approval of AZSTARYS™

Amendment Increases Total Potential Regulatory and Sales Milestone Payments to \$590 Million, and Adds a New Top-Level Tier for Royalties on U.S. Net Sales

Conference Call and Live Audio Webcast Scheduled for Today, Thursday, April 8, at 4:30 p.m. ET

Celebration, FL – April 8, 2021 – KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced an amendment to the definitive collaboration and license agreement (the License Agreement) with an affiliate of Gurnet Point Capital (GPC), a private investment firm focused on the life sciences and medical technology sectors. The License Agreement provides for an exclusive worldwide license to develop, manufacture and commercialize KemPharm’s product candidates containing serdexmethylphenidate (SDX) and d-methylphenidate (d-MPH), including 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 was approved by the U.S. Food and Drug Administration (FDA) on March 2, 2021.

Under the terms of the amended License Agreement, KemPharm is now eligible to receive a total of up to \$590 million in future regulatory and sales milestone payments for AZSTARYS, as well as tiered royalty payments on a product-by-product basis for net sales. Royalty rates range, on a product-by-product basis, from a percentage in the high single digits up to the mid-twenties for U.S. net sales, and a percentage in the low to mid-single digits of net sales in each country outside of the U.S. Under the original terms of the License Agreement, KemPharm was eligible to receive up to \$468 million in regulatory and sales milestones, having already received \$15 million from previously achieved milestones.

Per the amended terms, KemPharm will receive a regulatory milestone payment of \$10 million for the FDA approval of AZSTARYS which is due five (5) calendar days after the effective date of the amendment. In addition, KemPharm is eligible to receive an additional regulatory milestone payment of \$10 million within thirty (30) days following the scheduling determination of SDX, the prodrug component of AZSTARYS, by the U.S. Drug Enforcement Administration (DEA). The DEA action is expected to be completed on or around June 2, 2021. Other changes include the addition of four new sales milestone tiers, including three lower-level sales tiers and a new top level sales tier. Potential sales milestones available under the amended License Agreement total \$550 million, as compared to \$420 million in the original agreement. Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital (GPC), is leading the commercialization of AZSTARYS and expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

“The last few weeks since AZSTARYS was approved have been an exciting and busy time as we have worked with our partners at GPC and Corium to re-evaluate the commercial potential of AZSTARYS based on the final approved label, and negotiated adjustments to the economics of our License Agreement to optimize investment in the commercial launch and, ultimately, long-term value creation. The outcome is that more resources will be invested during the initial phases of the commercial timeline for AZSTARYS which we believe could lead to greater market share and potentially accelerate the ramp to peak, as compared to our original forecasts, if successful,” said Travis C. Mickle, Ph.D., President and CEO of KemPharm.

Dr. Mickle continued, “Our recently completed financial restructuring, by which we eliminated all of our debt and built a cash reserve of more than \$77 million, has provided KemPharm with the financial flexibility to work with GPC to re-allocate a portion of the original regulatory milestone amounts associated with FDA approval of AZSTARYS to the commercialization efforts underway at Corium. In exchange for re-allocating of a portion of the original regulatory milestone payments, the amended License Agreement now has a greater total value in terms of total regulatory and sales milestones, and increased royalty rates throughout the life of the patents that cover AZSTARYS, which extend to 2037.”

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

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation today, Thursday, April 8, 2021, at 4:30 p.m. ET, to discuss the amendments to the License Agreement. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 3593808

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 today, April 8, 2021, at approximately 5:30 p.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.

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: 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). KemPharm's lead clinical development candidate for the treatment of SUD, KP879, is based on its prodrug of d-methylphenidate, known as serdexmethylphenidate (SDX). In addition, KemPharm has received FDA approval for AZSTARYS™, a new once-daily treatment for ADHD in patients age six years and older, and 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](#).

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

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 the timing of the potential commercial launch of AZSTARYS, the potential greater market share and ramp to commercial peak, potential regulatory and sales milestone and royalty payments pursuant to the License Agreement, and the potential clinical benefits of AZSTARYS or any of the Company’s product candidates 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, 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.

KemPharm Contacts:

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KemPharm

Amendment to KP415 License Agreement

April 8, 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, 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.



Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **R. LaDuane Clifton, CPA** – Chief Financial Officer, Secretary & Treasurer



ASTARYS™ Approval

- ✓ **On March 2, 2021, the FDA approved 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
 - License Agreement with an affiliate of GPC provides significant economic benefits to KemPharm tied to the commercial launch of AZSTARYS
- ✓ **Approved label for AZSTARYS provides significant differentiation, which required a re-thinking of commercial forecasts and long-term possibilities**
 - The totality of various label elements, including administration, height and weight data from clinical trials experience, pharmacokinetics and efficacy data, all provide potential differentiation as compared to currently available d-MPH products for ADHD



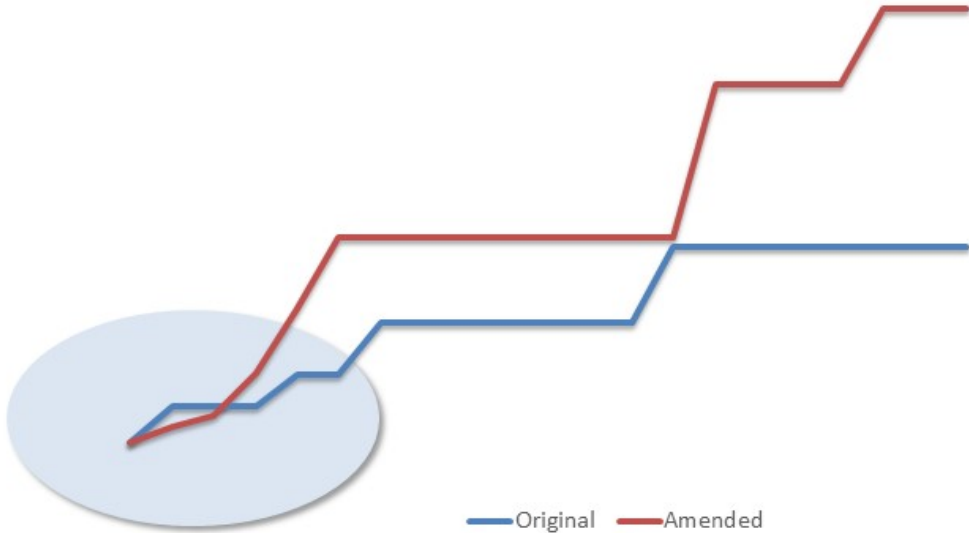
Amendment to License Agreement w/ Affiliate of GPC

- ✓ **Post-Approval commercial assessments conducted separately and together with the GPC team led to a renegotiation of the economic terms of the KP415 License Agreement**
 - Total potential regulatory and sales milestone payments increased to **\$590M** from \$468M (these are in addition to \$15M in upfront and NDA acceptance milestones already paid)
 - Added **new top-level sales tier for royalty rates** on U.S. net sales and **increased royalty rates throughout the life** of the patents that cover AZSTARYS through 2037. Those rates range, on a product-by-product basis, from a percentage in the high single digits up to the mid-twenties for U.S. net sales
 - KemPharm eligible to receive **\$10M** regulatory milestone payment for FDA approval of AZSTARYS; additional **\$10M** regulatory milestone following DEA scheduling determination of SDX (anticipated on or around June 2, 2021)
 - **Four additional sales milestone tiers added**, including three lower-level sales tiers and a new top-level sales tier
 - Sales milestones available under the amended License Agreement total **\$550M**, as compared to \$420M in the original agreement



Comparison of Potential Milestones

- Comparing the original and updated commercial forecasts, re-allocated early milestones have the potential to be re-captured quickly and potential for increase in total value



Focusing Resources on Commercialization of AZSTARYS™

- Amended terms allow GPC to re-allocate resources to Corium's efforts, with the goal to optimize the commercial launch
 - *More resources will be directed into the initial phases of the commercial timeline for AZSTARYS*
- Based on the approval label for AZSTARYS, we believe that peak market share may be greater than our original forecasts
 - *Additional investment in commercialization activities could potentially accelerate the ramp to peak, as compared to original forecasts*
- KemPharm's successful financial restructuring enabled KemPharm to negotiate a re-allocation of near-term milestone payments to optimize resources available from our partner for AZSTARYS commercialization
 - *In return, KemPharm has the potential to earn more in milestones and royalties throughout the life of the AZSTARYS patent, which extends to 2037*



AZSTARYS™ Commercial Updates from Corium

- Led by Perry Sternberg, Corium's President and CEO, as well as many other executives with prior Shire experience, Corium is building out a *best-in-class* ADHD sales and support organization
- Some payors have indicated initial receptivity to AZSTARYS and the differentiation that it may provide for patients
- GPC is providing strong support for the commercial launch, including expanding resources available to optimize initial and ongoing commercial activities



KemPharm: Operating from a Position of Strength

AZSTARYS™ (KP415) <ul style="list-style-type: none">- FDA has approved AZSTARYS NDA- Now eligible to receive up to \$590M for regulatory and sales milestone payments- Tiered royalties as percentage of U.S. net sales in the mid-twenties- Corium expected to launch in H2 2021	Improved Financial Position <ul style="list-style-type: none">- Multi-phase financial restructure process completed- KMPH stock re-listed on Nasdaq effective Jan 8, 2021- Debt repaid in full on Feb 8, 2021- Cash on hand as of Mar 10, 2021 = \$77.6M
Partnership Updates <ul style="list-style-type: none">- Consultation services agreement with Corium for projects other than AZSTARYS with revenue through Mar 2022- Collaboration between KVK-Tech and Sure Med Compliance for APADAZ® pilot program in Alabama launched Dec 1	Beyond KP415 <ul style="list-style-type: none">- Ongoing services agreement with Corium adds additional revenue- KP879 IND cleared by FDA; initiation of clinical trial program expected in 2021- KVK-Tech/Sure Med collaboration for APADAZ, Perspectives in Care program gaining traction

