UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): June 18, 2020

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	None

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. ☒

Explanatory Note

This Amendment No. 1 on Form 8-K/A is an amendment to the Current Report on Form 8-K, or the Form 8-K, of KemPharm, Inc., a Delaware corporation, or KemPharm, filed with the Securities and Exchange Commission on June 18, 2020. This Amendment No. 1 is being furnished for the sole purpose of including as an exhibit a corrected version of a press release as described in further detail in Item 7.01 below.

Item 7.01 Regulation FD Disclosure.

On June 18, 2020, KemPharm issued a press release announcing that Travis C. Mickle, Ph.D., President and CEO of KemPharm, issued a letter to shareholders in connection with KemPharm's 2020 Annual Meeting of Stockholders to be held on June 19, 2020. The letter provided an update on recent events and outlook for 2020 and 2021. KemPharm is furnishing this amendment on Form 8-K/A to the Form 8-K to correct certain typographical errors contained in the original press release.

Specifically, the second sentence of the first paragraph following the heading “Financial Position and Listing Status” should read as follows: “We expect this trend to continue through 2021 as we continue to work with our partners to advance the development of our various product candidates and, if approved, to support the commercial launch of KP415 potentially during the second half of 2021.” In addition, the third sentence of the same paragraph should read as follows: “The combination of continuing services revenue, an improved expense base, completing the first phase of restructuring our debt obligations, and the $5 million regulatory milestone earned under the KP415/KP484 License Agreement as a result of the FDA’s acceptance of the KP415 NDA, has extended our cash runway past the potential March 2, 2021 PDUFA date for the KP415 NDA and up to the debt maturity date of March 31, 2021.”

A copy of the corrected press release is furnished as Exhibit 99.1 to this Amendment No. 1 on Form 8-K/A.

The information contained in this Item 7.01, and the press release furnished as Exhibit 99.1, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Issues Letter to Shareholders” dated June 18, 2020.

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: June 18, 2020

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

Exhibit 99.1

KemPharm Issues Letter to Shareholders

Celebration, FL – June 18, 2020 – KemPharm, Inc. (OTCQB: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that Travis C. Mickle, Ph.D., President and CEO of KemPharm, has issued a Letter to Shareholders in connection with the Company's 2020 Annual Meeting of Stockholders to be held on June 19, 2020. The letter provides an update on recent events and outlook for the remainder of 2020 and early 2021.

The full text of the letter follows below.

A MESSAGE FROM OUR CHAIRMAN AND CHIEF EXECUTIVE OFFICER

Dear Fellow Shareholders:

The last twelve months have been a period of significant advancement for KemPharm. While challenges certainly remain, there are also significant reasons for optimism. Just recently, the New Drug Application ("NDA") for KP415, our investigational product candidate for the treatment of attention deficit hyperactivity disorder ("ADHD"), was successfully filed and accepted by the U.S. Food and Drug Administration ("FDA"). In addition, we recently received Day-74 Letter from the FDA which set the action date ("PDUFA") for KP415 as March 2, 2021. I am also pleased to pass along that there were no information requests included in the letter from the FDA that were not already expected, and the FDA informed us that an advisory committee is not required at this time.

The FDA's acceptance of the KP415 NDA has triggered two important developments in our collaboration with Gurnet Point Capital ("GPC") and its affiliates. First, KemPharm earned and has since received the $5 million milestone payment as provided by the definitive collaboration and license agreement we entered into with an affiliate of GPC on September 3, 2019 (the "KP415/KP484 License Agreement"). Second, we were pleased to announce Corium, Inc. ("Corium"), a GPC portfolio company, will lead all commercialization activities for KP415.

Corium is led by several executives with significant experience in the commercialization of ADHD products, including its President and Chief Executive Officer, Perry Sternberg. Mr. Sternberg previously served a dual role at Shire Plc ("Shire") as the Head of U.S. Commercial for seven therapeutic area business units, as well as the Chief Commercial Officer/Head of the Neuroscience Division, prior to the acquisition of Shire by Takeda Pharmaceutical Corporation Limited. During his tenure at Shire, Mr. Sternberg was responsible for bringing forth several groundbreaking ADHD products, including Vyvanse®.

Working with our existing debtholders, led by Deerfield Management ("Deerfield"), we were also able to complete an initial restructuring of our outstanding debt in December 2019, which allowed us to extend all principal and interest payments to a new maturity date of March 31, 2021, which is past the PDUFA date for KP415. This has extended our cash runway and allows us to capitalize on the opportunities that arise from the KP415/KP484 License Agreement and the potential approval of KP415 to negotiate a long-term restructure of our balance sheet.

Based on these recent events and accomplishments, we are very optimistic about KemPharm's short- and long-term prospects. This enthusiasm is rooted in three core beliefs:

1) KP415, if approved, has the potential to reshape the ADHD treatment landscape, particularly the methylphenidate product market;

2) Corium possesses the most well-suited and experienced commercial organization to launch and maximize the potential market for KP415; and

3) Addressing KemPharm's debt is an achievable goal.

The ADHD Market Opportunity – KP415 and KP484

The ADHD market accounts 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 (MPH) portion of the ADHD market accounted for approximately 20 million prescriptions and $4.9 billion in sales. Over the last several years, Jornay PM® (marketed by Ironshore Pharmaceuticals, Inc.) is the only new MPH product that has been introduced to the market. However, our research suggests that prescribers and patients remain eager for truly innovative new treatment options. KP415 is based on serdexmethylphenidate ("SDX"), which is KemPharm's prodrug of d-methylphenidate, which, if approved, would be the first prodrug of methylphenidate made available to the ADHD market.

KemPharm designed both KP415 and KP484 to specifically target several key unmet needs with the most widely prescribed MPH treatments for ADHD. With respect to KP415, its target design attributes include improving onset of action, providing consistent therapy with a longer duration, and reducing abuse potential. Based on the data obtained from KP415's clinical program, we believe these design goals have been met. Now, we are collaborating with Corium to support the NDA review process which will determine the final label for KP415, and, if approved, to bring these potential benefits to the ADHD market.

While KP415 is designed to be used across several age groups and with a variety of patient types, KP484 is more specifically aimed at post-adolescent patients who require a full-day treatment option for their ADHD symptoms. KP484 is included in the KP415/KP484 License Agreement, and the team at Corium is actively evaluating the potential value and timing of the product development plan. We will share material updates with you as we receive them.

I am also pleased to inform you that several additional patents for SDX were issued over the past few months which we expect will allow continued intellectual property ("IP") protection for SDX and any product containing SDX, until at least the year 2037. The potential to have a 16-year product life from PDUFA is a truly unique opportunity arising from the underlying prodrug IP and is exciting when considering the lifetime commercial potential of KP415.

For those who closely follow the ADHD space, products with the expected attributes of KP415 and KP484 are highly desirable given the lack of innovation in the market over the last 15 years. Not since Vyvanse® was approved in 2007 has there been a product brought to market with significantly new properties or benefits. It is this vast potential, as well as the collective abilities and experience of KemPharm's development team, that enabled us to secure the KP415/KP484 License Agreement, and through that, have the opportunity for the Corium team, led by Mr. Sternberg, to spearhead the commercialization of KP415.

GPC and Corium: History and Outlook

As I mentioned previously, KemPharm entered into the KP415/KP484 License Agreement in September 2019, which provided GPC and its affiliates exclusive worldwide rights to develop, manufacture and, if approved, commercialize product candidates containing SDX and d-MPH, including KP415 and KP484. The terms of the deal entitle KemPharm to earn up to $493M in milestone payments, which includes a $10 million upfront payment, a $5 million regulatory milestone payment upon the FDA's acceptance of the KP415 NDA, approval milestone payments related to KP415 and KP484 of up to $58 million, and royalties on U.S. net sales of up to 25%, and royalties on ex-U.S. net sales of up to 9%. In addition, GPC will provide reimbursements of up to $8 million in third-party product development costs for KP415 and all future development costs for KP484. Further, the KP415/KP484 License Agreement provides GPC the option to license two additional prodrug candidates from KemPharm: KP879 for the treatment of Stimulant Use Disorder, and KP922, our prodrug of amphetamine for the treatment of ADHD.

In addition, KemPharm earns research and development services revenue under the KP415/KP484 License Agreement, and Q1 2020 marked KemPharm's third sequential quarter of reporting such revenue. We expect to continue generating revenue into the foreseeable future as we support the potential launch of KP415 and the potential development of KP484. Under the KP415/KP484 License Agreement, our next milestone payment will be earned if the KP415 is approved on its PDUFA date of March 2, 2021. The amount of the milestone payment will be based on KP415's final approved label.

With all of the economic opportunity available to KemPharm under the KP415/KP484 License Agreement, the true value of KemPharm's relationship with GPC cannot be measured entirely in dollars and cents. GPC and Corium are motivated by a strong belief in the potential of KP415 and KemPharm's other product candidates to transform the ADHD treatment landscape. This enthusiasm was clearly evident as we worked closely with the GPC team during all phases of preparing the KP415 NDA for submission to the FDA. Our collaboration led to what we believe is a strong NDA package for KP415. This outlook was affirmed by the FDA in the Day-74 letter, which stated that the KP415 NDA is "...sufficiently complete to permit a substantive review..." Both KemPharm and the GPC team were very pleased that there were no unexpected questions or requests for clarifications in the letter.

In Corium, KemPharm has aligned with what we believe is the best organization to lead the potential commercialization of KP415. Mr. Sternberg and his team have successfully commercialized numerous products targeting large patient populations, and their expertise in the ADHD space is unmatched. Success in anything is never a certainty, but the more experience, knowledge and passion one possesses, the greater the likelihood of achieving one's goals. Working with Corium, and backed by GPC, we believe that KP415 is in prime position to capture a sizeable portion of the ADHD market and bring meaningful benefits to physicians, patients and their families. We look forward to working together with our partners at GPC and Corium to support the ongoing regulatory process and commercial preparation activities needed to facilitate a potential launch of KP415 in the second half of 2021, if approved.

Development Pipeline and APADAZ®

Now that the KP415 NDA is under FDA review, we have begun working with the team at Corium to determine the next steps in advancing our other product candidates, which includes KP484, KP879 and KP922.

After KP415, KP484 is our next most advanced product. In many ways, the clinical development program for KP484 is expected to mirror the KP415 program. However, we expect to gain important time and cost efficiencies since KP484 is also based on our prodrug, SDX. For example, we plan to reference certain pharmacokinetic data, as well as the results of the human abuse potential trials from the KP415 program in a potential future NDA for KP484.

The advancement of KP879 and KP922, as well as KP484, will depend on input from GPC and Corium. KP879 is ready for us to submit an Investigational New Drug application ("IND") with the FDA, and, if given the go-ahead, we could submit that IND later this year. Similar to both KP415 and KP484, each of our other pipeline product candidates has the potential to fulfill key unmet needs in their respective target patient populations. In fact, KP879 is the first product candidate to be designed and developed to treat stimulant use disorder (also known as "SUD"). As such, it may qualify for Fast-Track status with the FDA, as well as potentially be designated as a Breakthrough Therapy and/or Orphan Drug. These designations could potentially enable a priority review process with the FDA and possibly lead to other development and cost-saving advantages.

In addition to KemPharm's current product development pipeline, we are working with Deerfield to identify up to two additional compounds where KemPharm's Ligand Activated Therapy (LAT®) technology could be applied to develop new prodrug candidates that address unmet needs. Deerfield has a history of supporting the development and commercialization of innovative drug therapies and is uniquely positioned with its network of portfolio companies to identify and evaluate the commercial potential of various product candidates across a broad spectrum of therapeutic areas. We believe that the debt restructuring activities that occurred in December 2019, combined with their interest in future investment in prodrug discovery, demonstrates that Deerfield remains a solid financial partner that continues to value the long-term potential of KemPharm's team, technology and future product opportunities.

With regard to APADAZ®, KemPharm continues to work closely with our licensing partner, KVK-Tech, Inc. ("KVK"). Despite the challenging environment for prescription opioids, KVK has made important progress in several areas. Specifically, KVK made APADAZ available nationally through its distributor network for pharmacies to stock beginning in November 2019, 23 states have added the authorized generic form of APADAZ to their Medicaid preferred drug lists, and just recently, APADAZ and its authorized generic was added to the Federal Supply Schedule (known as the "FSS"). We are encouraged by this progress and hope to continue providing material updates as we received them from KVK.

Financial Position and Listing Status

As I noted above, Q1 2020 was our third consecutive quarter of development services revenue. We expect this trend to continue through 2021 as we continue to work with our partners to advance the development of our various product candidates and, if approved, to support the commercial launch of KP415 potentially during the second half of 2021. The combination of continuing services revenue, an improved expense base, completing the first phase of restructuring of our debt obligations, and the $5 million regulatory milestone earned under the KP415/KP484 License Agreement as a result of the FDA's acceptance of the KP415 NDA, has extended our cash runway past the potential March 2, 2021 PDUFA date for the KP415 NDA and up to the debt maturity date of March 31, 2021.

Beginning in early 2019, we have undertaken measures to improve our financial position, including a 36% reduction in our workforce, as well as other G&A cost reductions, shifting development costs to our partners, and adding development services revenue. We are continuing to work with our financial advisors to complete the second phase of debt restructuring, which we will seek to complete, if possible, prior to the potential approval of the KP415 NDA. While challenging, we remain optimistic that a solution is possible. As a fellow shareholder and the first investor, I remain focused on addressing this issue in the most favorable manner possible to us.

Regarding our listing status with Nasdaq, on May 19, 2020, KemPharm received a letter from the Nasdaq Hearings Panel notifying us that since it was unable to regain compliance with the $35 million minimum market value of listed securities requirement by May 13, 2020, the Hearings Panel had elected to delist the Company's shares from trading on Nasdaq. In response, we submitted, and OTC Markets accepted, KemPharm's application for trading of its common shares on the OTC Markets Venture Market (the "OTCQB"), where our shares have continued trading under the same ticker symbol, "KMPH."

Throughout the Nasdaq appeals process, KemPharm explored many options, including highly dilutive financings and reverse stock splits that could potentially assist in maintaining our listing on Nasdaq. However, after careful evaluation, we determined that the measures necessary to fulfill the Nasdaq listing requirements would not serve the longer-term interests of the Company or its shareholders. Our hope is that the multiple, near-term growth opportunities related to KP415 and our development pipeline could provide momentum for KemPharm to potentially return to trading on Nasdaq, or potentially other alternatives that become available.

Closing Thoughts

We at KemPharm have accomplished a great deal over the last several months, but significant challenges remain to be overcome. Compared to a year ago, the Company's financial footing is much better, but our work in that regard continues. The KP415 NDA is now under FDA review with March 2, 2021 established as the PDUFA date, and as a result, Corium and its seasoned team of executives are now working full force to develop the marketing and commercialization strategy for KP415, which we look forward to unveiling in the not-too-distant future. It is inspiring to be part of such an effort.

We are optimistic about KemPharm's future, and for good reason. Despite numerous headwinds, KemPharm has advanced to several important milestones and is positioned for continued success. All this has been made possible by the diligent efforts of our team and our partners. We would like to thank our employees for their dedication and loyalty. Most importantly, we thank you, our Shareholders, for your continued support as we advance through the FDA review process for KP415 and plan for the next phase of growth at KemPharm.

Sincerely,

Travis C. Mickle, Ph.D.
Chairman, President, Chief Executive Officer and Shareholder
KemPharm, Inc.

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.

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 the Company'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 the timing and probability of potential FDA approval of the KP415 NDA, the potential commercial launch of KP415, the potential clinical benefits of KP415 or any of our product candidates, the expectations regarding continued development services revenue, the potential initiation or timeline for the development of any of our product candidates, our cash runway and the ability to continue as a going concern, and the timeline to complete a debt restructuring, if at all, 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, 2019, 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.

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