KemPharm Issues Letter to Shareholders

June 16, 2021 11:30 AM EDT

CELEBRATION, Fla., June 16, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on 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 2021 Annual Meeting of Stockholders to be held on June 17, 2021. The letter provides an update on recent events and outlook for the remainder of 2021 and early 2022.

The full text of the letter follows.

A MESSAGE FROM OUR CHAIRMAN AND CHIEF EXECUTIVE OFFICER

Dear Fellow Shareholders:

KemPharm is a company transformed, and I write to you today as excited about our future as I have been since the Company's founding in 2006. AZSTARYS™ has been approved by the U.S. Food and Drug Administration ("FDA"), and we continue to work closely with our partners at Gurnet Point Capital ("GPC") and Corium, Inc. ("Corium") to ready its launch as a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older. In parallel, we have completed a substantial financial restructuring that removed all debt from our balance sheet and brought in both dilutive and non-dilutive cash to bolster our balance sheet. As of March 31, 2021, we reported a cash balance of $76.0 million, and have since received another $20 million in regulatory milestone payments under the license agreement with an affiliate of GPC (the "License Agreement"). In conjunction with these transactions, KemPharm has regained its listing on The Nasdaq Capital Market and, as we recently announced, our stock is expected to be added to the Russell 2000® and Russell 3000® Indexes effective June 28, 2021, which should serve to further drive investor interest.

In short, we have met or exceeded all of the goals set forth in our 2020 shareholder letter, and, as a result, KemPharm is poised for what has the potential to be a period of sustained growth. I am pleased to share with you all that has been accomplished and what is soon expected.

AZSTARYS – A Differentiated Product Nearing Commercial Launch

The FDA approval of AZSTARYS in March was a watershed moment for KemPharm and an equally important advancement in the treatment of ADHD. The ADHD industry, and specifically the methylphenidate (MPH) space, has seen little innovation in recent years, leaving prescribers and patients desiring new treatment options. In our estimation, the product label for AZSTARYS is potentially best-in-class, with several elements in the label providing clear points of differentiation from other commercially available methylphenidate-based ADHD treatments.

Given this, the teams at GPC, Corium and KemPharm are extremely optimistic about AZSTARYS' market potential and are actively preparing the product for commercial launch, which is expected in the coming months. Recognizing an important opportunity to seize momentum with AZSTARYS, the Licensing Agreement between KemPharm and an affiliate of GPC was amended to redirect certain upfront milestone payments back to the commercialization effort. In exchange, the total potential regulatory and sales milestone payments for KemPharm were increased to $590 million from $468 million with four new sales milestone tiers and a new top-level tier for royalties added.

We view this as a significant opportunity for KemPharm as the uptake for AZSTARYS could be strong given its differentiated product characteristics, which, we believe, directly address key needs described by prescribers, patients and payors. As such, we want to ensure a successful commercialization of AZSTARYS given its potential to generate substantial value for KemPharm shareholders.

Serdexmethylphenidate Classified as Schedule IV and New Chemical Entity

Adding to our optimism surrounding AZSTARYS was the recent Orange Book listing of six patents covering serdexmethylphenidate (SDX) and confirmation of its status as a new chemical entity (NCE). SDX is KemPharm's prodrug of d-methylphenidate (d-MPH) and the primary active pharmaceutical ingredient (API) in AZSTARYS. The determination that SDX is an NCE provides five years of market exclusivity, which expires on May 7, 2026. During the NCE exclusivity period, the FDA cannot approve a new drug application (NDA), an abbreviated new drug application (ANDA) or a 505(b)(2) application for another product based on the same API, regardless of indication. This added early market exclusivity allows the product to gain market share without the cost and distraction of generic filings and subsequent lawsuits to protect our AZSTARYS patent portfolio which extends to 2037.

Perhaps more substantial than that was the classification of SDX as a Schedule IV controlled substance by the U.S. Drug Enforcement Administration (DEA). This determination was based on an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of SDX by the U.S. Department of Health and Human Services (HHS), which concluded that "SDX is related in action and effect to the Schedule IV substance phentermine and can therefore be expected to have a similar potential for abuse." Notably, in its report, HHS affirmed that "in clinical studies, SDX demonstrated a lower potential for abuse when compared to d-MPH," a Schedule II controlled substance under the CSA.

While AZSTARYS is classified as a Schedule II controlled substance because it includes a 70:30 mixture of SDX (Schedule IV) and d-MPH (Schedule II), respectively, it is expected that the knowledge that SDX has been classified as a Schedule IV controlled substance will prove meaningful to healthcare providers and payors when considering the possible benefit of SDX's lower abuse potential with respect to AZSTARYS.

These two regulatory events – the Orange Book listing and Schedule IV classification of SDX – are meaningful to the potential of AZSTARYS, but have an even greater impact on our SDX pipeline including KP879, our extended-duration, agonist replacement therapy for the treatment of Stimulant Use Disorder (SUD), and KP1077, a potential treatment for rare disease of idiopathic hypersomnia. In particular, the Schedule IV classification of SDX is significant for KP879 given that physicians who are treating patients seeking to overcome addictions to cocaine, methamphetamine or other stimulants may be able to prescribe KP879, if approved, with the knowledge that the product candidate could have a significantly lower potential for abuse. We now look forward to initiating the clinical program for KP879 in the coming months after receiving FDA clearance for the Investigational New Drug (IND) application.

Financial Restructuring Removes Debt, Strengthens Balance Sheet

Dovetailing with the accomplishments related to AZSTARYS and SDX was the completion of an extensive financial restructuring, which enabled KemPharm to emerge as a Nasdaq-listed company with no debt and significant cash holdings on the balance sheet. As a result of these transactions, we had the financial strength to amend our Licensing Agreement with GPC, potentially enabling greater returns to KemPharm, while providing the Company with the resources needed to continue the development of KP879.

We are now in the process of evaluating ways in which to efficiently deploy our capital resources to generate additional value streams for our shareholders. There are many opportunities to explore, both internally and externally, and creating long-term value remains top of mind. Said another way, KemPharm is now in a growth mode, and with that, we are seeking to bring in the talent that will enable us to bolster our operations, advance our development pipeline, and potentially target new assets to in-license or acquire. With that, at the Company's Annual Meeting on June 17, 2021, we will be seeking shareholder approval of a proposal to right-size the Company's equity incentive plan, which we believe is imperative to enticing the best talent to join KemPharm, while retaining the excellent team that has brought us this far.

Looking Ahead

The outlook at KemPharm is extremely optimistic given what we have accomplished and what lays ahead. Central to this optimism is the anticipated commercialization of AZSTARYS. Our observations thus far of Perry Sternberg and the entire Corium team lead us to believe that the launch will be successful and has the potential to achieve a solid market position. Beyond AZSTARYS, we expect to soon initiate the clinical program for KP879 and advance its development as the first potential treatment for SUD. We are also exploring additional treatment opportunities with SDX given its unique properties, the strength of its IP estate, and Schedule IV classification. Meanwhile, our R&D programs built upon our LAT® prodrug technology platform are rapidly advancing.

All of this success has been made possible by the diligent efforts of our team and the support of our shareholders. Thank you one and all.

Sincerely,

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

End of the shareholder letter text.

2021 Annual Meeting of Stockholders:

The 2021 Annual Meeting of Stockholders of KemPharm, Inc. will be held Thursday, June 17, 2021, at 9:00 a.m., ET, virtually via the internet at www.meetingcenter.io/259728376. **To access the virtual meeting, stockholders must have the information printed in the proxy materials.** To vote your shares, stockholders must go online or request a paper copy of the proxy materials to receive a proxy card. Further information can be found in the proxy materials filed with the SEC on April 30, 2021, which can be accessed via https://investors.kempharm.com/financial-information/sec-filings.

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 patents 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.

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 timing of the potential commercial launch of AZSTARYS, the market outlook for AZSTARYS, the potential therapeutic benefits of AZSTARYS, the potential benefits of Orange Book listing for SDX-related patents, the potential benefits of NCE exclusivity of SDX, the potential benefits of DEA scheduling of SDX as a Schedule IV controlled substance, the clinical development of KP879 and KP1077, the potential of greater returns under the amended License Agreement with GPC, and the potential addition to and benefits of inclusion on the Russell 2000® and Russell 3000® Indexes, 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 March 31, 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.

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