KemPharm Reports First Quarter 2021 Financial Results

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Corporate and Regulatory Highlights

- AZSTARYS™ NDA approved by the FDA on March 2, 2021
- Announced amendment to Licensing Agreement with Gurnet Point Capital affiliate following FDA approval of AZSTARYS
- Received FDA clearance to initiate KP879 clinical program for the treatment of Stimulant Use Disorder
- Serdexmethylphenidate (SDX) classified as a Schedule IV Controlled Substance by the DEA

Financial Highlights

- Completed financial restructuring, which resulted in re-listing on The Nasdaq Capital Market, receipt of approximate gross proceeds of $94 million and no debt
- Reported Q1 2021 revenue of $12.1 million
- Q1 2021 net loss of ($0.54) per basic share and diluted share compared to a net loss of ($1.92) per basic share and diluted share for Q1 2020
- Total cash, cash equivalents and restricted cash was $76.0 million at March 31, 2021

CELEBRATION, Fla., May 13, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today reported its financial results for the first quarter ended March 31, 2021.

“The first quarter of 2021 was nothing short of transformational for KemPharm, highlighted by the FDA approval of AZSTARYS, the completion of our financial restructuring, and the re-listing of our shares on Nasdaq,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “As a result, we stand today as a company with a solid balance sheet and capital structure that is moving full force with our partners at GPC and Corium to soon launch AZSTARYS as a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older.”

Dr. Mickle continued, “Following the close of the quarter, KemPharm further strengthened its position by agreeing to amend the License Agreement with an affiliate of GPC. We are now eligible to receive 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. This is a significant increase from the original License Agreement and also provides an opportunity to adjust the economics of the License Agreement to optimize investment in the commercial launch of AZSTARYS. Ultimately, we believe this arrangement has the opportunity to produce significant shareholder value based on the market outlook for AZSTARYS.”

Dr. Mickle continued, “As we have noted in prior communications, KemPharm believes that 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 ADHD products. We were pleased with the recent determination that serdexmethylphenidate (SDX), was classified as a Schedule IV controlled substance by the Drug Enforcement Administration (DEA) following a thorough review by the U.S. Department of Health and Human Services (HHS). SDX comprises 70% of the active pharmaceutical ingredient (API) in AZSTARYS, which is classified as a Schedule II controlled substance. In short, the agencies determined that SDX has a generally low potential for abuse and a lower potential for abuse when compared to d-MPH, a Schedule II controlled substance. Having SDX designated as a Schedule IV controlled substance, we believe, potentially increases AZSTARYS’ appeal among prescribers and patients.”

Dr. Mickle concluded, “Further, the Schedule IV classification of SDX is a significant development for our lead clinical product candidate, KP879, an extended-duration, agonist replacement therapy for the treatment of Stimulant Use Disorder (SUD), as SDX is the only API in KP879. We now look forward to initiating the clinical program for KP879 in 2021 after receiving FDA clearance for the Investigational New Drug (IND) application. If approved, KP879 could be a Schedule IV product, and physicians who are treating patients seeking to overcome addictions to cocaine, methamphetamine or other stimulants may be able to prescribe KP879 with the knowledge that the product candidate could have a significantly lower potential for abuse.”

Q1 2021 Financial Results:

For Q1 2021, KemPharm reported revenue of $12.1 million, which was primarily derived from a $10 million milestone payment earned upon the AZSTARYS NDA approval and service fee revenue of $2.1 million, as compared to Q4 2020 revenue of $2.4 million, which was derived primarily from service fee revenue. Current consulting arrangements contractually continue through March 2022.

KemPharm’s net loss for Q1 2021 was $10.3 million, or $0.54 per basic share and diluted share, compared to net loss of $5.8 million, or $1.92 per basic and diluted share for the same period in 2020. Net loss for Q1 2021 was driven primarily by a non-cash loss on extinguishment of debt of $16.9 million and net interest expense and other items of $0.4 million, partially offset by operating income of $7.0 million. The net operating income of $7.0

million for Q1 2021 was a change of $10.7 million compared to net operating loss of $3.8 million in the same period in 2020, which was primarily due to an increase in revenue of $10.0 million related to the milestone payment and a net decrease in operating expenses of $0.7 million period over period. The net decrease in operating expenses was primarily due to a decrease in severance expense of $0.8 million and a decrease in general and administrative expenses of $0.4 million, partially offset by an increase in royalty and direct contract acquisition costs of $0.3 million and an increase is research and development expenses of $0.1 million.

As of March 31, 2021, total cash, cash equivalents and restricted cash was $76.0 million, which was an increase of $71.7 million compared to December 31, 2020. The increase was driven by the Company's multi-phase financial restructure process which was completed during the quarter.

As of March 31, 2021, total shares of common stock outstanding was 28,480,156 shares, and fully diluted common shares outstanding was 38,379,718 shares, which included 9,544,693 shares issuable upon exercise of warrants. In addition, no preferred stock is outstanding as of March 31, 2021.

"KemPharm has emerged from Q1 2021 as a Nasdaq-listed company with no debt and significant cash holdings on the balance sheet," said LaDuane Clifton, KemPharm's Chief Financial Officer. "We have the resources needed to continue the development of KP879, and we have begun evaluating how to efficiently deploy capital to generate additional value streams for shareholders. There are many opportunities to explore, both internally and externally, and creating long-term value is top of mind."

Conference Call Information:

Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 4737008

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 at approximately 5:30 p.m. ET, on May 13, 2021.

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 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, potential regulatory and sales milestone and royalty payments pursuant to the License Agreement with an affiliate of GPC, the potential benefits of AZSTARYS and the clinical development of KP879, 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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KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2021	2020
Revenue	$ 12,117	$ 2,089
Operating expenses:		
Royalty and direct contract acquisition costs	1,000	663
Research and development	2,265	2,126
General and administrative	1,892	2,245
Severance expense	—	830
Total operating expenses	5,157	5,864
Income (loss) from operations	6,960	(3,775)
Other (expense) income:		
Loss on extinguishment of debt	(16,885)	—
Interest expense related to amortization of debt issuance costs and discount	(150)	(571)
Interest expense on principal	(199)	(1,260)
Fair value adjustment related to derivative and warrant liability	(30)	75
Interest and other income (expense), net	8	(223)
Total other expenses	(17,256)	(1,979)
Loss before income taxes	(10,296)	(5,754)
Income tax benefit (expense)	—	—
Net loss	$ (10,296)	$ (5,754)
Deemed dividend	(37,444)	—
Net loss attributable to common stockholders	$ (47,740)	$ (5,754)
Basic and diluted net loss per share of common stock:		
Net loss	$ (0.54)	$ (1.92)
Net loss attributable to common stockholders	$ (2.49)	$ (1.92)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	19,146,270	3,004,559

KEMPHARM, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and par value amounts)

	March 31, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 75,917	$ 4,213
Accounts and other receivables	11,308	2,579
Prepaid expenses and other current assets	395	1,481
Restricted cash	109	109
Total current assets	87,729	8,382
Property and equipment, net	975	1,039
Operating lease right-of-use assets	1,294	1,350
Other long-term assets	437	438
Total assets	$ 90,435	$ 11,209
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,855	$ 6,647
Current portion of operating lease liabilities	336	327
Current portion of loans payable	683	390
Other current liabilities	364	172
Total current liabilities	4,238	7,536
Convertible notes, less current portion, net	—	67,658
Derivative and warrant liability	334	304
Operating lease liabilities, less current portion	1,500	1,587
Loans payable	98	391
Other long-term liabilities	14	145
Total liabilities	6,184	77,621
Stockholders’ equity (deficit):		

Preferred stock, undesignated, $0.0001 par value, 9,957,366 shares authorized, no shares issued or outstanding as of March 31, 2021 (unaudited); 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2020	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 28,480,156 shares issued and outstanding as of March 31, 2021 (unaudited); 4,537,321 shares issued and outstanding as of December 31, 2020	3	—
Additional paid-in capital	353,018	192,062
Accumulated deficit	(268,770)	(258,474)
Total stockholders' equity (deficit)	84,251	(66,412)
Total liabilities and stockholders' equity (deficit)	$ 90,435	$ 11,209

Source: KemPharm