KemPharm Reports Second Quarter 2021 Financial Results

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Corporate and Regulatory Highlights

- U.S. Commercial Launch of AZSTARYS™ Initiated on July 21, 2021
- Serdexmethylphenidate (SDX) Classified as a Schedule IV Controlled Substance by the DEA
- Announced Orange Book Listing for Six Patents Covering SDX and Confirmation of NCE Status
- KemPharm Added to Russell 2000® and Russell 3000® Indexes

Financial Highlights

- Q2 2021 net income of $0.18 per basic share
- Reported Q2 2021 revenue of $12.0 million
- Confirmed receipt of $10 million milestone payment for DEA scheduling of SDX
- Total cash and cash equivalents was $132.3 million at June 30, 2021

CELEBRATION, Fla., Aug. 12, 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 second quarter ended June 30, 2021.

“The second quarter of 2021 and recent weeks continued what has been a period of unprecedented growth and opportunity for KemPharm, highlighted by the U.S. commercial launch of AZSTARYS,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “AZSTARYS, previously KP415, was conceived based on the vision that our LAT® technology was well-suited to developing a prodrug of d-methylphenidate (d-MPH) that could address key patient and prescriber demands that were underserved by ADHD products on the market at the time. Today that vision is a reality, and as the commercial rollout of AZSTARYS by Corium continues, ADHD patients and their caregivers will have the opportunity to benefit from the unique attributes inherent only to AZSTARYS. It is a truly exciting time for KemPharm and, we believe, for the millions of patients seeking a better treatment option for their ADHD symptoms.”

Dr. Mickle continued, “In addition to the commercial launch of AZSTARYS, the second quarter was highlighted by the classification of serdexmethylphenidate (SDX) as a Schedule IV controlled substance by the Drug Enforcement Administration (DEA). SDX comprises 70% of the active pharmaceutical ingredient (API) in AZSTARYS, which is classified as a Schedule II controlled substance. Importantly, the classification of SDX as a Schedule IV controlled substance and the unique properties of SDX, we believe, provide us the opportunity to develop an SDX-based product candidate or candidates that could potentially address disease indications for which no therapy currently exists. We have recently initiated a clinical trial with SDX, and in the coming months we expect to report clinical data together with an SDX development plan. Based on the results of the clinical trial, this plan may involve one or more potential product candidates that have the potential to generate substantial near-term and longer-range value for the Company.”

Q2 2021 Financial Results:

For Q2 2021, KemPharm reported revenue of $12.0 million, which was comprised of a $10.0 million milestone payment earned upon the DEA scheduling of SDX, and service fee revenue of $2.0 million, as compared to Q2 2020 revenue of $6.9 million, which was derived primarily from a $5.0 million milestone payment earned upon U.S. Food and Drug Administration (FDA) acceptance of the AZSTARYS New Drug Application (NDA) and service fee revenue. The service fee revenue is being earned under consulting arrangements which contractually continue through March 2022.

KemPharm’s net income for Q2 2021 was $6.2 million, or $0.18 per basic share. Recognition of a non-cash deemed dividend of $16.9 million related to the warrant exercise inducement transaction in June 2021 led to a ($10.7) million net loss attributable to common stockholders and diluted shares, or ($0.40) per basic share attributable to common stockholders and diluted share for Q2 2021, compared to net income of $0.9 million, or $0.21 per basic and diluted share for the same period in 2020. Net income for Q2 2021 was driven primarily by operating income of $5.8 million and a non-cash gain on extinguishment of debt of $0.8 million related to the forgiveness of the PPP loan, partially offset by non-cash fair value adjustment loss of $0.4 million related to derivative and warrant liability. The net operating income of $5.8 million for Q2 2021 was a change of $3.2 million compared to net operating income of $2.6 million in the same period in 2020, which was primarily due to an increase in revenue of $5.1 million and a net increase in operating expenses of $1.8 million period over period. The net increase in operating expenses was primarily due to increases in research and development expense of $0.9 million, general and administrative expenses of $0.6 million and royalty and direct contract acquisition costs of $0.4 million.

As of June 30, 2021, total cash and cash equivalents was $132.3 million, which was an increase of $56.4 million compared to March 31, 2021.

As of June 30, 2021, total shares of common stock outstanding was 34,977,923 shares, and fully diluted common shares outstanding was 46,546,998 shares, which included 4,584,889 shares issuable upon exercise of warrants. In addition, no preferred stock is outstanding as of June 30, 2021.

Conference Call Information:

KemPharm will host a conference call and live audio webcast on Thursday, August 12, 2021, at 4:30 p.m. ET, to discuss its corporate and financial results for Q2 2021.

Telephone Access: To access the conference call telephonically, interested participants and investors are required to register via the following online form: http://www.directeventreg.com/registration/event/2069253

Once registered, all individuals will be provided with participant dial-in numbers, a passcode and a registrant ID, which can then be used to access the conference call.

Participants may register at any time. It is recommended that the registration process be completed at least 15 minutes prior to the start of the call.

Webcast Access: The live audio webcast with slide presentation will be accessible via the Investor Relations section of KemPharm'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 August 12, 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 potential benefits of AZSTARYS, and the potential commercial success of AZSTARYS, 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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenue	$ 11,986	$ 6,908	$ 24,103	$ 8,997
Operating expenses:				
Royalty and direct contract acquisition costs	1,000	642	2,000	1,305
Research and development	2,848	1,954	5,113	4,080
General and administrative	2,305	1,719	4,197	3,964
Severance expense	—	—	—	830
Total operating expenses	6,153	4,315	11,310	10,179
Income (loss) from operations	5,833	2,593	12,793	(1,182)
Other income (expense):				
Gain (loss) on extinguishment of debt	789	—	(16,096)	—
Interest expense related to amortization of debt issuance costs and discount	—	(574)	(150)	(1,145)
Interest expense on principal	(16)	(1,197)	(215)	(2,457)
Fair value adjustment related to derivative and warrant liability	(394)	(3)	(424)	72

Interest and other (expense) income, net	(9)	40	(1)	(183)
Total other income (expense)	370	(1,734)	(16,886)	(3,713)
Income (loss) before income taxes	6,203	859	(4,093)	(4,895)
Income tax benefit (expense)	—	—	—	—
Net income (loss)	$ 6,203	$ 859	$ (4,093)	$ (4,895)
Deemed dividend	(16,898)	—	(54,342)	—
Net (loss) income attributable to common stockholders	$ (10,695)	$ 859	$ (58,435)	$ (4,895)
Basic net income (loss) per share of common stock:				
Net income (loss)	$ 0.18	$ 0.21	$ (0.17)	$ (1.41)
Net income (loss) attributable to common stockholders	$ (0.40)	$ 0.21	$ (2.42)	$ (1.41)
Diluted net income (loss) per share of common stock:				
Net income (loss) attributable to common stockholders	$ (0.40)	$ 0.21	$ (2.42)	$ (1.43)
Weighted average number of shares of common stock outstanding:				
Basic	29,174,565	3,947,656	24,187,484	3,476,107
Diluted	29,174,565	3,947,728	24,187,484	3,476,107

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

	June 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 132,295	$ 4,213
Accounts and other receivables	1,888	2,579
Prepaid expenses and other current assets	1,998	1,481
Restricted cash	—	109
Total current assets	136,181	8,382
Property and equipment, net	992	1,039
Operating lease right-of-use assets	1,187	1,350
Other long-term assets	437	438
Total assets	$ 138,797	$ 11,209
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,973	$ 6,647
Current portion of operating lease liabilities	342	327
Current portion of loans payable	—	390
Other current liabilities	2,644	172
Total current liabilities	5,959	7,536
Convertible notes, less current portion, net	—	67,658
Derivative and warrant liability	728	304
Operating lease liabilities, less current portion	1,413	1,587
Loans payable	—	391
Other long-term liabilities	34	145
Total liabilities	8,134	77,621
Commitments and contingencies (Note D)		
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 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, 34,977,923 shares issued and outstanding as of June 30, 2021 (unaudited); 4,537,321 shares issued and outstanding as of December 31, 2020	3	0
Additional paid-in capital	393,227	192,062
Accumulated deficit	(262,567)	(258,474)
Total stockholders' equity (deficit)	130,663	(66,412)
Total liabilities and stockholders' equity (deficit)	$ 138,797	$ 11,209

Source: KemPharm