KemPharm Reports First Quarter 2022 Financial Results and Corporate Updates

May 12, 2022 8:05 PM EDT

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, May 12, 2022, at 5:00 p.m. ET

- Filed Investigational New Drug (IND) application with U.S. Food and Drug Administration (FDA) for KP1077, a serdexmethylphenidate (SDX)-based product candidate for idiopathic hypersomnia (IH)
  - Initiation of a Phase 2 trial (KP1077.D01) expected in the second half of 2022, with a second trial in patients with narcolepsy expected to begin the quarter following start of KP1077.D01
- Dosed first patient in Phase 1 clinical trial evaluating cardiovascular safety of SDX compared to immediate-release and long-acting formulations of Ritalin® (racemic methylphenidate)
- Total cash, cash equivalents, marketable securities and long-term investments was $119.1 million as of March 31, 2022

CELEBRATION, Fla., May 12, 2022 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a specialty pharmaceutical company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS) and neurodegenerative diseases, today reported its financial results for the first quarter ended March 31, 2022.

"KemPharm continued to make significant progress during the first quarter of 2022 and recent weeks, in particular taking several important steps to further the clinical development of our SDX-based drug candidates led by KP1077," stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "In keeping with our strategic focus on developing and commercializing therapeutics for rare CNS and neurodegenerative conditions, we filed an IND with the FDA seeking permission to commence a clinical program to evaluate KP1077 for IH, a rare sleep disorder with limited treatment options. Upon clearance of the IND, we plan to initiate a Phase 2 clinical trial of KP1077 for IH (KP1077.D01) as early as the second half of 2022, with a second trial in narcolepsy targeted to begin the quarter following the start of KP1077.D01."

Dr. Mickle continued, "We believe there is great potential for KP1077 and other SDX-based treatments in IH and the broader rare sleep disorder market. Stimulant-based drugs currently in use come with significant limitations, including cardiovascular side effects, such as elevated blood pressure which results in many of these treatments being contraindicated for many IH patients. Understanding this, we initiated a Phase 1 trial last month comparing the cardiovascular safety of SDX to immediate-release and long-acting formulations of Ritalin, a commonly prescribed CNS stimulant. We believe that demonstrating an improved cardiovascular safety profile compared to current stimulants is a key potential differentiator for KP1077. This benefit could allow SDX to be dosed at higher levels than current treatments which should provide improved efficacy when compared to other off-label stimulant-based medications."

Dr. Mickle continued, "We are also excited by the growing momentum behind the national commercialization of AZSTARYS® by Corium. Payor access continues to expand with 110 million commercial lives now covered and prescription volumes continue to grow as well. More than 2,600 pharmacies have dispensed AZSTARYS, and it is listed on formularies by two of the three largest PBMs in the U.S. We look forward to watching the progress of AZSTARYS as our partners at Corium continue the U.S. launch."

Dr. Mickle concluded, "On the business development front, we continue to pursue our goal of acquiring or licensing complimentary clinical-stage assets in rare CNS and neurodegenerative diseases where we can leverage our existing clinical development and regulatory expertise. Internally, we are advancing several early-stage candidates and hope to announce a potential addition to our development pipeline as soon as this quarter. Supporting our strategic and pipeline development efforts is a strong financial foundation, bolstered by $119.1 million in cash, cash equivalents, marketable securities and long-term investments as of March 31, 2022."

Q1 2022 Financial Results:

KemPharm's revenue for Q1 2022 was $4.0 million, as compared to Q1 2021 revenue of $12.1 million.

Research and development expenses were $3.1 million for Q1 2022, as compared to $2.3 million in Q1 2021, driven primarily by the initiation of the KP1077 clinical development program.

General and administrative expenses were $2.7 million for Q1 2022, as compared to $1.9 million in Q1 2021. The period-over-period increase was primarily driven by increased compensation costs, including non-cash stock-based compensation, and an increase in professional fees associated with commercial and strategic planning.

Net loss attributable to common stockholders for Q1 2022 was ($1.9) million, or ($0.05) per basic and diluted share, compared to a net loss attributable to common stockholders of ($47.7) million, or ($2.49) per basic and diluted share for the same period in 2021. Net loss for Q1 2022 was driven primarily by a loss from operations of ($1.9) million and net interest and other loss of ($0.2) million, partially offset by non-cash fair value adjustment income related to derivative and warrant liability of $0.2 million.

As of March 31, 2022, total cash, cash equivalents, marketable securities and long-term investments was $119.1 million, which was a decrease of $8.7 million compared to $127.8 million as of December 31, 2021, driven in part by $4.7 million of repurchases of common stock during the period and

increased spending on third-party research and development costs related to the KP1077 clinical trial program. Based on the Company's current operating forecast, existing cash, cash equivalents, marketable securities and long-term investments are expected to be sufficient to continue operations through and beyond 2025.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with a slide presentation today at 5:00 p.m. ET, to discuss its corporate and financial results for the first quarter of 2022.

Telephone Access:	To access the conference call telephonically, interested participants and investors will be required to register via the following online form: http://www.directeventreg.com/registration/event/1133056. 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 6:00 p.m. ET, on Wednesday, May 12, 2022.

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of novel treatments for rare central nervous system (CNS) diseases through its proprietary LAT® (Ligand Activated Therapy) platform technology. KemPharm utilizes its proprietary LAT® platform 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 idiopathic hypersomnia (IH) and other CNS/rare diseases. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a once-daily treatment for ADHD in patients age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S., and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S. 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation and which can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "could," "intend," "target," "predict," or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding the promise and potential impact of our preclinical or clinical trial data, including without limitation the timing and results of any clinical trials or readouts, the timing or results of any IND applications, the potential uses or benefits of KP1077, SDX or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of KemPharm's product candidates, the success or timing of the launch or commercialization of AZSTARYS or any other products or related sales milestones, the sufficiency of cash to fund operations, our plans or ability to seek funding, our plans with respect to our share repurchase program, and our strategic and product development objectives. 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 known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2021, as updated by the Quarterly Report on Form 10-Q for the three months ended March 31, 2022, and KemPharm's other filings with the Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

This press release 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.

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KEMPHARM, INC.

UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2022	**2021**
Revenue	$ 3,965	$ 12,117

Operating expenses:		
Royalty and direct contract acquisition costs	8	1,000
Research and development	3,082	2,265
General and administrative	2,734	1,892
Total operating expenses	5,824	5,157
(Loss) income from operations	(1,859)	6,960
Other (expense) income:		
Loss on extinguishment of debt	—	(16,885)
Interest expense related to amortization of debt issuance costs and discount	—	(150)
Interest expense on principal	(5)	(199)
Fair value adjustment related to derivative and warrant liability	241	(30)
Interest and other (expense) income, net	(245)	8
Total other expenses	(9)	(17,256)
Loss before income taxes	(1,868)	(10,296)
Income tax benefit	4	—
Net loss	$ (1,864)	$ (10,296)
Deemed dividend	—	(37,444)
Net loss attributable to common stockholders	$ (1,864)	$ (47,740)
Basic and diluted net loss per share of common stock:		
Net loss attributable to common stockholders	$ (0.05)	$ (2.49)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	34,506,597	19,146,270

KEMPHARM, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share and par value amounts)

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 100,242	$ 112,346
Marketable securities	1,338	—
Accounts and other receivables	3,320	1,528
Prepaid expenses and other current assets	880	1,182
Total current assets	105,780	115,056
Property and equipment, net	835	884
Operating lease right-of-use assets	1,090	1,141
Long-term investments	17,564	15,422
Other long-term assets	437	438
Total assets	$ 125,706	$ 132,941
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,582	$ 3,038
Current portion of operating lease liabilities	356	356
Other current liabilities	7	836
Total current liabilities	2,945	4,230
Derivative and warrant liability	89	330
Operating lease liabilities, less current portion	1,144	1,232
Other long-term liabilities	29	31
Total liabilities	4,207	5,823
Stockholders' equity:		
Preferred stock:		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2022 (unaudited) or December 31, 2021	—	—
Common stock, $0.0001 par value, 250,000,000 shares authorized, 35,333,450 shares issued and 34,423,497 shares outstanding as of March 31, 2022 (unaudited); 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021	3	4
Additional paid-in capital	397,925	396,957
Treasury stock, at cost	(7,536)	(2,814)
Accumulated deficit	(268,893)	(267,029)

Total stockholders' equity	121,499	127,118
Total liabilities and stockholders' equity	$ 125,706	$ 132,941

Source: KemPharm