KemPharm Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Corporate Updates

March 30, 2022 8:05 PM EDT

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, March 30, 2022, 5:00 p.m. ET

Corporate and Regulatory Highlights

- Announced strategic focus on developing and commercializing therapeutics targeting rare central nervous system (CNS) and neurodegenerative conditions;
- Advancing development of KP1077, a serdexmethylphenidate (SDX) based product candidate for idiopathic hypersomnia (IH), as KemPharm's lead candidate:
  - Pre-Investigational New Drug (IND) process with the U.S. Food and Drug Administration (FDA) successfully completed in February 2022;
  - IND filing expected as early as the second quarter of 2022; Phase 2 trial initiation expected in the second half of 2022; and
  - Reported data from the Phase 1 clinical trial exploring the safety and pharmacokinetics (PK) of "higher-dose" SDX which validates selection of KP1077 as lead product candidate.
- AZSTARYS® national launch accelerating; full national sales team in place as of January 31, 2022, growing payor access;
- KemPharm named 2021 David J. Gury Company of the Year by BioFlorida; and
- Earned $1.975 million fee in first quarter of 2022 following FDA approval of Corium, Inc.'s product, ADLARITY®.

Financial Highlights

- Reported quarter ended December 31, 2021 (Q4 2021) revenue of $2.6 million and FY 2021 revenue of $28.7 million; and
- Total cash, cash equivalents and long-term investments was $127.8 million as of December 31, 2021.

CELEBRATION, Fla., March 30, 2022 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a specialty pharmaceutical company focused on the discovery and development of novel treatments for rare central nervous system (CNS) diseases, today reported its financial results for the fourth quarter and year ended December 31, 2021.

"KemPharm advanced on multiple fronts during the fourth quarter of 2021 and into early 2022, cementing the past twelve months as the most substantial in KemPharm's history," stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "In January, we announced our strategic focus on developing and commercializing therapeutics targeting rare CNS and neurodegenerative conditions starting with KP1077. The data released earlier this month from the Phase 1 clinical trial exploring the safety and PK of 'higher dose SDX,' affirms the opportunity to develop multiple SDX-based drug candidates, led by KP1077 for the treatment of IH, a rare sleep disorder with limited treatment options. Our recent interactions with the FDA have confirmed that we may proceed with the submission of an IND application for KP1077, which we expect to file as early as the second quarter of 2022. Upon clearance of the IND, we plan to initiate a Phase 2 clinical trial of KP1077 in IH later this year with a second trial in narcolepsy targeted to begin as early as the second half of 2022. In addition, we remain active on the business development front with the goal of acquiring or licensing complimentary clinical stage assets in rare CNS and neurodegenerative diseases."

"As KemPharm focuses on advancing KP1077 and expanding our development pipeline, we remain bullish on the potential for the commercial success of AZSTARYS®, which is now being commercialized nationally by Corium. There have been significant gains in payor access, and prescription volume is beginning to grow. If this growth continues along the same trajectory observed since the beginning of 2022, the potential to achieve the initial sales milestones provided in the licensing agreement with an affiliate of Gurnet Point Capital becomes more tangible."

"Supporting these strategic and product development efforts is our strong financial position. With $127.8 million in cash, cash equivalents and long-term investments as of December 31, 2021, our current capital resources enable us to advance our internal pipeline while also potentially seeking external opportunities. The strength of our capital position sets us apart from many other development-stage biopharmaceutical companies, particularly in this challenging capital market environment. Our existing $50 million share repurchase program, which extends through 2023, also

provides a mechanism to return value to shareholders as we achieve success."

Q4 and Full-Year 2021 Financial Results:

KemPharm's revenue for Q4 2021 was $2.6 million, as compared to Q4 2020 revenue of $2.4 million. Q4 2021 revenue was derived primarily from $2.0 million in service fee revenue, and approximately $0.6 million of various royalty payments under the license agreement which covers AZSTARYS. The contracts under which service fee revenue is derived will end on March 31, 2022, although some amount of service fee revenue is expected to continue beyond that date.

KemPharm's net loss for Q4 2021 was ($2.7) million, or ($0.08) per basic and diluted share, compared to a net loss of ($4.9) million, or a loss of ($1.07) per basic and diluted share for the same period in 2020. Net loss for Q4 2021 was driven primarily by a loss from operations of ($2.8) million, partially offset by net interest and other income of $0.1 million. The net operating loss of ($2.8) million for Q4 2021 was a decrease of ($0.4) million compared to net operating loss of ($3.2) million in the same period in 2020.

For FY 2021, KemPharm reported revenue of $28.7 million, which was primarily driven by $20.6 million in milestone and royalty revenue received under the license agreement which covers AZSTARYS, and approximately $8.1 million derived under service fee arrangements and related reimbursements. FY 2020 revenue was $13.3 million.

KemPharm's net loss attributable to common stockholders for FY 2021 was ($62.9) million, or ($2.11) per basic and diluted share, compared to net loss attributable to common stockholders of ($12.8) million, or ($3.21) per basic and diluted share for FY 2020. Net loss attributable to common stockholders for FY 2021 was driven primarily by aggregate non-cash deemed dividends of ($54.3) million, or ($1.83) per basic and diluted share, which were recognized as a result of the warrant inducement transactions completed in the first half of 2021, a non-cash net loss on extinguishment of debt of ($16.1) million, or ($0.54) per basic and diluted share related to the debt extinguishment in Q1 2021, partially offset by net income from operations of $7.7 million.

As of December 31, 2021, total cash, cash equivalents and long-term investments was $127.8 million, which was a decrease of $3.7 million compared to $131.5 million as of September 30, 2021, driven in part by share repurchases of $2.4 million which were settled during Q4 2021. Based on the Company's current operating forecast, existing cash, cash equivalents 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 slide presentation today at 5:00 p.m. ET, to discuss its corporate and financial results for the fourth quarter of 2021 and fiscal year of 2021.

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/8038872. 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, March 30, 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 new once-daily treatment for ADHD in patents 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 benefits of KP1077, SDX or any other product candidates for any specific disease indication, 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, 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.

KemPharm Contacts:

Tiberend Strategic Advisors, Inc.
Jason Rando/Daniel Kontoh-Boateng
jrando@tiberend.com
dboateng@tiberend.com

KEMPHARM, INC.

STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2021 (unaudited)	**2020**
Revenue	$ 28,650	$ 13,288
Operating expenses:		
Royalty and direct contract acquisition costs	2,059	1,305
Research and development	10,161	8,843
General and administrative	8,701	7,921
Severance expense	-	828
Total operating expenses	20,921	18,897
Income (loss) from operations	7,729	(5,609)
Other (expense) income:		
Loss on extinguishment of debt	(16,096)	-
Interest expense related to amortization of debt issuance costs and discount	(150)	(2,305)
Interest expense on principal	(226)	(4,785)
Fair value adjustment related to derivative and warrant liability	(26)	(184)
Interest and other income, net	248	89
Total other expense	(16,250)	(7,185)
Loss before income taxes	(8,521)	(12,794)
Income tax (expense) benefit	(34)	34
Net loss	(8,555)	(12,760)
Deemed dividend	(54,342)	-
Net loss attributable to common stockholders	$ (62,897)	$ (12,760)
Basic net loss per share of common stock:		
Net loss attributable to common stockholders	$ (2.11)	$ (3.21)
Diluted net loss per share of common stock:		
Net loss attributable to common stockholders	$ (2.11)	$ (3.21)
Weighted average number of shares of common stock outstanding:		
Basic	29,766,347	3,980,975
Diluted	29,766,347	3,980,975

KEMPHARM, INC.

BALANCE SHEETS

(in thousands, except share and par value amounts)

	December 31,	
	2021 (unaudited)	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 112,346	$ 4,213
Accounts and other receivables	1,528	2,579
Prepaid expenses and other current assets	1,182	1,481
Restricted cash	-	109
Total current assets	115,056	8,382
Property and equipment, net	884	1,039

Operating lease right-of-use assets	1,141	1,350
Long-term investments	15,422	-
Other long-term assets	438	438
Total assets	$ 132,941	$ 11,209
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,038	$ 6,647
Current portion of operating lease liabilities	356	327
Current portion of loans payable	-	390
Other current liabilities	836	172
Total current liabilities	4,230	7,536
Convertible notes, less current portion, net	-	67,658
Derivative and warrant liability	330	304
Operating lease liabilities, less current portion	1,232	1,587
Loans payable, less current portion	-	391
Other long-term liabilities	31	145
Total liabilities	5,823	77,621
Stockholders' equity (deficit):		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2020	-	-
Series B-1 convertible preferred stock, $0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 1,576 shares authorized and issued and no shares outstanding as of December 31, 2020	-	-
Series B-2 convertible preferred stock, $0.0001 par value, no shares authorized, issued or outstanding as of December 31, 2021; 27,000 shares authorized and issued and no shares outstanding as of December 31, 2020	-	-
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2021; 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, 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021; 4,537,321 shares issued and outstanding as of December 31, 2020	4	0
Additional paid-in capital	396,957	192,062
Treasury stock, at cost	(2,814)	-
Accumulated deficit	(267,029)	(258,474)
Total stockholders' equity (deficit)	127,118	(66,412)
Total liabilities and stockholders' equity (deficit)	$ 132,941	$ 11,209

Source: KemPharm