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KemPharm Reports Third Quarter 2021 Financial Results and Corporate Updates

November 10, 2021 9:05 PM EST

Lead Independent Director Richard W. Pascoe Named Executive Chairman

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, November 10, 2021, 4:30 p.m. ET

Corporate and Regulatory Highlights

- Appointment of Richard W. Pascoe as Executive Chairman; Mr. Pascoe to focus on executing the Company's strategic growth plans
- Uplisted to The Nasdaq Global Select Market
- Research involving AZSTARYS[®] and serdexmethylphenidate featured in poster presentations at multiple medical conferences during ADHD Awareness Month (October)
 - Data presented during the 2021 Virtual International Conference on ADHD affirmed AZSTARYS' 30-minute onset of action and 13-hour duration of effect
- Appointed Tamara A. Seymour to Board of Directors
- U.S. commercial launch of AZSTARYS initiated on July 21, 2021

Financial Highlights

- Q3 2021 net loss of \$0.05 per basic share
- Reported Q3 2021 revenue of \$2.0 million
- Total cash and cash equivalents was \$131.5 million at September 30, 2021

CELEBRATION, Fla., Nov. 10, 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 third quarter ended September 30, 2021. In addition, the Company announced that Richard W. Pascoe, lead independent director on the Board of Directors, has been named Executive Chairman to support execution of the Company's strategic growth objectives to expand its pipeline and commercialization capabilities. Travis C. Mickle, Ph.D., remains the Company's President and Chief Executive Officer, and as a member of the Board of Directors.

"I am delighted to partner with Rich in his new role as Executive Chairman as we build upon our successful track record of clinical development and U.S. regulatory approvals to create an innovative biopharmaceutical company with an expanded pipeline and commercial capabilities," stated Dr. Mickle. "Rich and I have built a strong working relationship since he joined our Board in 2014, and I am proud of our many accomplishments at KemPharm to date. Working together to expand the Company's growth opportunities will be exciting as together we pursue our shared goal to increase shareholder value."

"I am excited for the opportunity to continue my service to KemPharm as its Executive Chairman and to partner with Travis and the executive team as we seek to grow into a profitable, fully integrated, biopharmaceutical company," said Mr. Pascoe. "Travis, the Board of Directors, and I are committed to this objective which we will seek to accomplish by successfully building, developing, and commercializing a pipeline of innovative product candidates focused on the treatment of neurodegenerative/central nervous system indications."

Mr. Pascoe has a strong track record building and leading life sciences organizations. He has served in key leadership roles in companies that successfully raised over \$300 million in equity capital, taken private companies public, closed more than \$2 billion of value in business development transactions, obtained regulatory approvals for two products in both the U.S. and Europe, and led commercial launches of prescription drugs in the U.S. across multiple therapeutic categories.

Most recently, Mr. Pascoe served as Chief Executive Officer of Histogen Inc., and his prior experiences include serving as Chief Executive Officer at Apricus Biosciences Inc. and Somaxon Pharmaceuticals, Inc. Mr. Pascoe's career is also highlighted by several senior management roles, including Chief Operating Officer at ARIAD Pharmaceuticals, Inc., and Senior Vice President of the Neuroscience Division at King Pharmaceuticals, Inc. In addition to serving as Executive Chairman of KemPharm, Inc., Mr. Pascoe is currently a member of the board of directors of Seelos Therapeutics, Inc., and the board of directors of the Johnny Mac Soldiers Fund, a charity for military veterans. Mr. Pascoe is a graduate of the Unites States Military Academy at West Point.

Q3 2021 Corporate and Financial Results:

"The third quarter of 2021 was highlighted by the U.S. commercial launch of AZSTARYS[®], a seminal event in KemPharm's history, which occurred during a year with numerous transformative milestones for the company," said Dr. Mickle. "Corium's commercialization of AZSTARYS continues to proceed as planned, and their team has recently reported to us their estimate that more than 50 million commercial and Medicaid lives now have access to AZSTARYS with more progress expected in the coming months. Additionally, research involving AZSTARYS and serdexmethylphenidate (SDX) was presented at three recent ADHD medical conferences, including data from the pivotal study of AZSTARYS demonstrating the drug's

30-minute onset-of-action and 13-hour duration-of-effect. At only 100 days post-launch, we are encouraged by the early progress, and we believe that Corium's commercialization efforts will continue to gain traction with payors, providers, prescribers and patients."

Dr. Mickle continued, "In addition to Rich's appointment as Executive Chairman, we also announced several other corporate advancements, including the appointment of Tamara Seymour to our Board of Directors and the uplisting of our common stock to The Nasdaq Global Select Market. These developments continue a period of transformation for KemPharm as we position ourselves to capitalize on pipeline development opportunities that, we believe, will ultimately translate to enhanced shareholder value. The advancement of our SDX program is also moving ahead, with data from the ongoing SDX clinical trial expected to be announced prior to year-end. This information will provide valuable insights into the potential path forward for developing SDX-based product candidates designed for therapeutic indications with underserved patient populations."

Financial results for Q3 2021 included revenue of \$2.0 million, as compared to Q3 2020 revenue of \$1.9 million, which was derived primarily from service fee revenue. The service fee revenue is being earned under consulting arrangements which contractually continue through March 2022.

KemPharm's net loss for Q3 2021 was \$1.8 million, or \$0.05 per basic share, compared to a net loss of \$3.0 million, or a loss of \$0.68 per basic and diluted share for the same period in 2020. Net loss for Q3 2021 was driven primarily by operating loss of \$2.2 million, partially offset by non-cash fair value adjustment income of \$0.3 million related to derivative and warrant liability and net interest income and other items of \$0.1 million. The net operating loss of \$2.2 million for Q3 2021 was a change of \$1.0 million compared to net operating loss of \$1.2 million in the same period in 2020, which was primarily due to increases in operating expenses period over period. The net increase in operating expenses was primarily due to increases in research and development expense of \$0.5 million and general and administrative expenses of \$0.5 million.

As of September 30, 2021, total cash and cash equivalents was \$131.5 million, which was a decrease of \$0.8 million compared to \$132.3 million as of June 30, 2021.

As of September 30, 2021, total shares of common stock outstanding was 35,317,313 shares, and fully diluted common shares outstanding was 46,553,727 shares, which included 4,252,600 shares issuable upon exercise of warrants. In addition, no preferred stock is outstanding as of September 30, 2021.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation on Wednesday, November 10, 2021, at 4:30 p.m. ET, to discuss its corporate and financial results for the third quarter 2021.

 Telephone
 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/6718737

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
 The live audio webcast with slide presentation will be accessible via the Investor Relations section of KemPharm's

 Access:
 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 November 10, 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). 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 <u>www.kempharm.com</u> or connect with us on <u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u> and <u>YouTube</u>.

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 continued commercialization of AZSTARYS and the further development of KemPharm's pipeline of product candidates, 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 other flings 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.

KemPharm Contacts:

KEMPHARM, INC. UNAUDITED CONDENSED STATEMENTS OF OPERATIONS (in thousands, except share and per share amounts)

| | т | | | nded September 30, | | | |
|--|----|------------|----|-----------------------|----------------|----|-----------|
| | | 2021 | | 2020 | 2021 | | 2020 |
| Revenue | \$ | 1,965 | \$ | 1,925 | \$ 26,068 | \$ | 10,922 |
| Operating expenses: | | | | | | | |
| Royalty and direct contract acquisition costs | | — | | — | 2,000 | | 1,305 |
| Research and development | | 2,239 | | 1,709 | 7,352 | | 5,789 |
| General and administrative | | 1,948 | | 1,429 | 6,145 | | 5,393 |
| Severance expense | | | | | _ | | 830 |
| Total operating expenses | | 4,187 | | 3,138 | 15,497 | | 13,317 |
| (Loss) income from operations | | (2,222) | | (1,213) | 10,571 | | (2,395) |
| Other income (expense): | | <u>.</u> | | | | | |
| Loss on extinguishment of debt | | _ | | _ | (16,096) | | _ |
| Interest expense related to amortization of debt issuance costs and discount | | — | | (578) | (150) | | (1,723) |
| Interest expense on principal | | (6) | | (1,163) | (221) | | (3,620) |
| Fair value adjustment related to derivative and warrant liability | | 332 | | (137) | (92) | | (65) |
| Interest and other income (expense), net | | 137 | | 48 | 136 | | (135) |
| Total other income (expense) | | 463 | | (1,830) | (16,423) | | (5,543) |
| Loss before income taxes | | (1,759) | | (3,043) | (5,852) | | (7,938) |
| Income tax benefit | | _ | | 34 | _ | | 34 |
| Net loss | | (1,759) | | (3,009) | (5,852) | | (7,904) |
| Deemed dividend | | | | | (54,342) | | |
| Net loss attributable to common stockholders | \$ | (1,759) | \$ | (3,009) | \$ (60,194) | \$ | (7,904) |
| Basic net loss per share of common stock: | | | | | | | |
| Net loss | \$ | (0.05) | \$ | (0.68) | \$ (0.21) | \$ | (2.08) |
| Net loss attributable to common stockholders | \$ | (0.05) | \$ | (0.68) | \$ (2.16) | \$ | (2.08) |
| Diluted net loss per share of common stock: | | | | | | | |
| Net loss attributable to common stockholders | \$ | (0.06) | \$ | (0.68) | \$ (2.16) | \$ | (2.08) |
| Weighted average number of shares of common stock outstanding: Basic | | 35,217,953 | | 4,425,474 | 27,904,711 | | 3,794,840 |
| Diluted | | 35,217,953 | | 4,425,474 | 27,904,711 | | 3,794,840 |

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

| | September 3 2021 | 0, I | December 31, 2020 |
|--|---------------------|----------|----------------------|
| | (unaudited |) | |
| Assets | | | |
| Current assets: | | | |
| Cash and cash equivalents | \$ 131,50 |)3 \$ | 4,213 |
| Accounts and other receivables | 1,6 | 9 | 2,579 |
| Prepaid expenses and other current assets | 1,50 |)8 | 1,481 |
| Restricted cash | | _ | 109 |
| Total current assets | 134,63 | 30 | 8,382 |
| Property and equipment, net | 93 | 31 | 1,039 |
| Operating lease right-of-use assets | 1,1 | 36 | 1,350 |
| Other long-term assets | 43 | 39 | 438 |
| Total assets | \$ 137,12 | 36 \$ | 11,209 |
| Liabilities and stockholders' equity (deficit) | | | |
| Current liabilities: | | | |
| Accounts payable and accrued expenses | \$ 2,04 | 35 \$ | 6,647 |
| Current portion of operating lease liabilities | 34 | 19 | 327 |

| Current portion of loans payable | _ | 390 |
|---|-------|--------|
| Other current liabilities | 1,264 | 172 |
| Total current liabilities | 3,698 | 7,536 |
| Convertible notes, less current portion, net | _ | 67,658 |
| Derivative and warrant liability | 396 | 304 |
| Operating lease liabilities, less current portion | 1,324 | 1,587 |
| Loans payable | _ | 391 |
| Other long-term liabilities | 31 | 145 |
| Total liabilities | 5,449 | 7,621 |
| | | |

Commitments and contingencies

Stockholders' equity (deficit): Preferred stock: Undesignated preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 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, 35,317,313 shares issued and outstanding as of September 30, 2021; 4,537,321 shares issued and outstanding as of December 31, 2020 4 Additional paid-in capital 396,059 192,062 (264,326) (258,474) Accumulated deficit Total stockholders' equity (deficit) 131,737 (66, 412)\$ Total liabilities and stockholders' equity (deficit) 137,186 \$ 11,209

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Source: KemPharm