KemPharm Reports Fourth Quarter and Full-Year 2020 Financial Results

March 11, 2021 9:25 PM EST

Corporate and Regulatory Highlights:

- AZSTARYS™ NDA approved by the FDA onMarch 2, 2021
- Co-hosted “KP415 Market Opportunity and Commercialization Strategy” Investor Event with Corium, Inc.
- Received FDA clearance to initiate KP879 clinical program for the treatment of Stimulant Use Disorder

Financial Highlights

- Completed financial restructuring and re-listed on The Nasdaq Capital Market, resulting in no debt and receiving gross proceeds of approximately $94 million
- Reported Q4 2020 revenue of $2.4 million and FY 2020 revenue of $13.3 million
- Q4 2020 net loss of ($1.07) per basic share and diluted share compared to a net loss of ($2.90) per basic share and diluted share for Q4 2019
- FY 2020 net loss of ($3.21) per basic and diluted share compared to a net loss of ($13.23) per basic and diluted share for the year ended December 31, 2019
- Total cash, cash equivalents and restricted cash was $77.6 million at March 10, 2021

CELEBRATION, Fla., March 11, 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 fourth quarter and year ended December 31, 2020.

“The fourth quarter of 2020 and early 2021 was a period of significant activity and accomplishment for KemPharm as the company has restructured its balance sheet, extinguished its debt, re-listed on The Nasdaq Capital Market and perhaps most importantly, received approval for the AZSTARYS NDA,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “Completing the multi-phased financial restructuring process was critically important during this timeframe, and bringing this together required a series of transactions that had to be orchestrated in a specific sequence. Now, combined with the approval of AZSTARYS, KemPharm is in a position of strength as we look forward to realizing the value from our development investments and the growth that is possible for the Company as a result.”

Dr. Mickle continued, “Now with the AZSTARYS approval behind us, we are working alongside the Corium team on the product’s commercial launch which is expected as early as the second half of 2021. As discussed during the December investor event, Corium is enthusiastic about AZSTARYS' potential as a treatment for ADHD with what we believe is a clear strategy for bringing the product to market.”

Dr. Mickle concluded, “We are also pleased to have received FDA clearance for the Investigational New Drug (IND) application for KP879, our extended-duration, agonist replacement therapy for the treatment of Stimulant Use Disorder (SUD). KP879 is an important addition to our product candidate portfolio as it provides an opportunity to address a disease indication – SUD – for which there are no FDA-approved medications, as well as to demonstrate the versatility and value potential of serdexmethylphenidate (SDX), our prodrug of d-methylphenidate. SDX is the primary API for KP879, as well as AZSTARYS and KP484, showcasing the potential for our prodrugs a platform technology. We now look forward to initiating the clinical program for KP879 in 2021.”

Q4 and Full-Year 2020 Financial Results:

For Q4 2020, KemPharm reported revenue of $2.4 million, which was primarily derived from service fee revenue, as compared to Q3 2020 revenue of $1.9 million, which was also primarily derived from service fee revenue. Current consulting arrangements are expected to provide service fee revenue through March 2022.

KemPharm’s net loss for Q4 2020 was ($4.9 million), or ($1.07) per basic share and diluted share, compared to net loss of ($6.0 million), or ($2.90) per basic and diluted share for the same period in 2019. Net loss for Q4 2020 was driven primarily by operating loss of ($3.2 million) and net interest expense and other items of ($1.6 million). The net operating loss of ($3.2 million) for Q4 2020 was a change of $1.2 million compared to net operating loss of ($4.4 million) in the same period in 2019, which was primarily due to a decrease in royalty and direct contract acquisition costs related to the KP415 License Agreement of $1.9 million and an increase is revenue of $1.0 million, partially offset by an increase in research and development expenses of $0.6 million and an increase in general and administrative expenses of $1.2 million.

For full-year 2020, KemPharm reported revenue of $13.3 million, which was primarily derived from service fee revenue and a milestone payment in Q2 2020 of $5.0 million related to the acceptance of the NDA by the FDA, as compared to full-year 2019 revenue of $12.8 million, which was also primarily derived from an upfront licensing fee payment of $10.0 million, as well as service fee and reimbursement revenue.

KemPharm’s net loss for full-year 2020 was ($12.8 million), or ($3.21) per basic share and diluted share, compared to net loss of ($24.5 million), or

($13.23) per basic and diluted share for the same period in 2019. Net loss for full-year 2020 was driven primarily by operating loss of ($5.6 million) and net interest expense and other items of ($7.2 million). The net operating loss of ($5.6 million) for full-year 2020 was a change of $14.7 million compared to net operating loss of ($20.3 million) in the same period in 2019, which was primarily due to a decrease in royalty and direct contract acquisition costs related to the KP415 license agreement of $1.6 million, a decrease in research and development expenses of $10.6 million, a decrease in general and administrative expenses of $2.9 million and an increase in revenue of $0.4 million, partially offset by severance expense of $0.8 million related to the departure of the chief business officer in Q1 2020.

As of December 31, 2020, total cash, cash equivalents and restricted cash was $4.3 million, which was a decrease of $1.1 million compared to September 30, 2020. As a result of the Company's completion of its multi-phase financial restructure process discussed below, total cash, cash equivalents and restricted cash as of March 10, 2021 was $77.6 million. The Company believes that, based on its current operating forecast, without taking into account expected service fee and reimbursement revenues, royalty revenues or milestone payments, its existing resources are sufficient to continue operations up to at least Q1 2024.

Multi-Phase Financial Restructure Process Completed

In early 2021, KemPharm completed a series of transactions as part of its long-term initiative to restructure its balance sheet and fundamentally improve the Company's financial position in pursuit of its ongoing goal to create shareholder value. Starting with debt of $93.1 million, net of discounts, as of March 31, 2018, the Company began a long-term process to address its debt, entering into a variety of debt exchanges and other transactions that have steadily reduced, and now provided the means to completely eliminate, its outstanding debt. In addition, the Company has regained its listing on The Nasdaq Capital Market.

In December 2019, the Company completed the first phase of its financial restructuring process entering into certain amendments to its debt agreements to extend the debt maturity dates to March 31, 2021. The Company also entered into a debt exchange agreement with Deerfield, allowing for the conversion of approximately $17.1 million of nominal debt into a combination of preferred and common shares, which was completed on August 10, 2020. After receiving shareholder authorization for the Company's Board to effect a reverse stock split, the Company entered the second phase of its financial restructuring process. The following provides a brief summary of the transactions recently completed:

- On December 20, 2020, the Company entered into an Exchange Agreement with Deerfield, which provided that upon completion of an equity offering of at least $40 million, Deerfield would exchange additional debt into equity. In addition, the maturity date for the remainder of the debt would be extended to March 31, 2023. Subsequently, on December 28, 2020, the Company reported that its other lenders, Delaware Street Capital and Kingdon Capital (together with Deerfield, the Lenders) had joined the Exchange Agreement.

- On December 23, 2020, a reverse stock split of 1-for-16 shares was made effective.

- On January 8, 2021, the Company announced pricing of a follow-on equity offering of $50 million, at a price of $6.50 per share, with an issuance of a combination of common shares and pre-funded warrants to purchase 7,692,307 common shares, as well as the issuance of warrants to purchase an additional 7,692,307 common shares at an exercise price of $6.50 per share (the Offering Warrants). This transaction closed on January 12, 2021, with net proceeds to the Company of approximately $46.4 million after underwriting discounts and commissions.

- On January 8, 2021, shares of the Company's common stock were re-listed and began trading on The Nasdaq Capital Market.

- On January 12, 2021, pursuant to the Exchange Agreement, the Company made a cash debt repayment of $30.3 million to the Lenders and completed the exchange of approximately $31.5 million of debt into preferred shares, leaving a remainder debt amount of approximately $7.6 million with a maturity date of March 31, 2023.

- On January 26, 2021, the Company announced a warrant exercise inducement transaction with certain of holders of the Offering Warrants, whereby such holders agreed to exercise for cash the Offering Warrants to purchase 6,620,358 shares of the Company's common stock in exchange for the Company's agreement to issue new warrants (the Inducement Warrants) to purchase up to 7,944,430 shares of the Company's common stock, which is equal to 120% of the number of shares of the Company's common stock issued upon exercise of the Offering Warrants. As a result of this transaction, the Company received gross proceeds of approximately $44.0 million.

- On February 8, 2021, the Company used approximately $8.0 million of the proceeds from the warrant exercise inducement transaction to repay the remaining debt, including the related prepayment premium.

In summary, the multi-step capital reorganization has allowed KemPharm to emerge as a Nasdaq listed company with no debt and significant cash holdings on the balance sheet.

As of March 10, 2021, total shares of common stock outstanding was 28,376,321 shares, and fully diluted common shares outstanding was 38,605,700 shares, which included 9,645,193 shares issuable upon exercise of warrants.

In connection with the transactions described above, the Company issued warrants exercisable for 21,775,269 shares of common stock. As of March 10, 2021, warrants totaling 12,281,518 have been exercised for 11,850,538 shares of common stock. These totals are inclusive of the 926,844 of pre-funded warrants issued in connection with underwritten offering, the 6,620,358 of Existing Warrants exercised as part of the warrant exercise inducement transaction and the 7,944,430 of Inducement Warrants subsequently issued as a result of the closing of the warrant exercise inducement transaction.

In addition, as of March 10, 2021, all preferred shares which arose from the debt restructuring transactions described above have been converted into common shares totaling 4,842,699 shares of common stock. No preferred stock is outstanding as of March 10, 2021.

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: 4085483

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 March 11, 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 serdexmethylphnidate (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, including without limitation our proposed development and commercial timelines, 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 expectations regarding continued research and development services revenue, the potential clinical benefits of AZSTARYS or any of the Company's product candidates, the potential initiation or timeline for the development of any of our product candidates, and cash runway, 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 September 30, 2020, 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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STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2020	**2019**
Revenue	$ 13,288	$ 12,839
Operating expenses:		
Royalty and direct contract acquisition costs	1,305	2,945
Research and development	8,843	19,415
General and administrative	7,921	10,816
Severance expense	828	-
Total operating expenses	18,897	33,176
Loss from operations	(5,609)	(20,337)
Other (expense) income:		
Interest expense related to amortization of debt issuance costs and discount	(2,305)	(1,656)
Interest expense on principal	(4,785)	(4,858)
Fair value adjustment related to derivative and warrant liability	(184)	1,998
Interest and other income, net	89	309
Total other (expense) income	(7,185)	(4,207)
Loss before income taxes	(12,794)	(24,544)
Income tax benefit	34	22
Net loss	$ (12,760)	$ (24,522)
Net loss per share of common stock:		
Basic and diluted	$ (3.21)	$ (13.23)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	3,980,975	1,853,397

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 4,213	$ 3,217
Accounts and other receivables	2,579	1,865
Prepaid expenses and other current assets	1,481	1,552
Restricted cash	109	338
Total current assets	8,382	6,972
Property and equipment, net	1,039	1,471
Operating lease right-of-use assets	1,350	1,537
Other long-term assets	438	527
Total assets	$ 11,209	$ 10,507
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,647	$ 4,911
Current portion of operating lease liabilities	327	284
Current portion of loans payable	390	-
Other current liabilities	172	236
Total current liabilities	7,536	5,431
Convertible notes, less current portion, net	67,658	77,343
Derivative and warrant liability	304	120
Operating lease liabilities, less current portion	1,587	1,901
Loans payable, less current portion	391	-
Other long-term liabilities	145	168
Total liabilities	77,621	84,963
Stockholders' deficit:		
Preferred stock:		
Series A convertible preferred stock, $0.0001 par value, 9,578 shares authorized, 9,577 shares issued and no shares outstanding as of December 31, 2020 and 2019	-	-
Series B-1 convertible preferred stock, $0.0001 par value, 1,576 shares authorized, 1,576 shares issued and no shares outstanding as of December 31, 2020 and 2019	-	-
Series B-2 convertible preferred stock, $0.0001 par value, 27,000 shares authorized, no shares issued or outstanding as of December 31, 2020 and 2019	-	-

Undesignated preferred stock, $0.0001 par value, 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2020 and 2019	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 4,537,321 shares issued and outstanding as of December 31, 2020; 2,271,882 shares issued and outstanding as of December 31, 2019	0	0
Additional paid-in capital	192,062	171,258
Accumulated deficit	(258,474)	(245,714)
Total stockholders' deficit	(66,412)	(74,456)
Total liabilities and stockholders' deficit	$ 11,209	$ 10,507

Source: KemPharm