
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 2016

KEMPHARM, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36913
(Commission File Number)

20-5894398
(IRS Employer
Identification No.)

**2656 Crosspark Road, Suite 100
Coralville, IA**

(Address of Principal Executive Offices)

52241
(Zip Code)

Registrant's Telephone Number, Including Area Code: (319) 665-2575

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On May 12, 2016, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended March 31, 2016, as well as information regarding a conference call to discuss these corporate and financial results. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of KemPharm’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm, Inc. Reports First Quarter 2016 Results” dated May 12, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KEMPHARM, INC.

Date: May 12, 2016

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton
Chief Financial Officer

Exhibit Index

Exhibit No.

Description

99.1

Press Release titled "KemPharm, Inc. Reports First Quarter 2016 Results" dated May 12, 2016.



KemPharm, Inc. Reports First Quarter 2016 Results

Conference Call and Live Audio Webcast Scheduled for Today at 4:30 p.m. ET

Recent Clinical Development & Regulatory Highlights:

- Introduced Apadaz™ as the proprietary name for KP201/APAP
- FDA Advisory Committees voted 16 to 4 in support of Apadaz approval; voted 18 to 2 against inclusion of abuse deterrent labeling
- Granted “Fast Track” designation for, and received clearance from FDA to initiate human clinical trials of KP511, KemPharm’s prodrug of hydromorphone

Recent Corporate and Financial Highlights:

- Expanded senior leadership team with the appointment of Daniel L. Cohen, Executive Vice President, Government and Public Relations, and Rene A. Braeckman, Ph.D., Vice President, Clinical Development
- Granted a fee waiver and received the refund of the full user fee amount of \$2.4 million for the Apadaz NDA
- Net loss of \$0.20 per basic and diluted share for the quarter ended 3/31/2016
- Cash, cash equivalents and marketable securities balance was \$111.0 million at 3/31/2016, an increase of \$59.7 million from 12/31/2015

Coralville, IA – May 12, 2016 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today reported its corporate and financial results for the first quarter ended March 31, 2016.

“This has been a significant period for KemPharm. Last week’s joint advisory committee meeting with the FDA’s Anesthetic and Analgesic Drug Products and Drug Safety and Risk Management committees voted in support of approving Apadaz for the management of acute pain that requires an opioid, yet recommended against including abuse deterrent labeling for the product,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “While the committees’ advice regarding potential product labeling is disappointing, we continue to work collaboratively with the FDA as it continues its priority review of Apadaz as we look ahead to the target action date on June 9, 2016.”

“Earlier this week we received Fast Track designation by the FDA for KP511, our prodrug of hydromorphone, for treatment of moderate-to-severe pain where an opioid is appropriate, and we now anticipate sharing proof-of-concept study data of KP511 as early as the second quarter of 2016. We believe these are positive steps forward with this program and demonstrate the continued development of our pipeline of proprietary prodrugs. Our plan is to develop KP511 as an extended-release prodrug product candidate – KP511/ER – that could offer the potential

to deter certain methods of abuse while providing the same pharmacokinetic and therapeutic effect as existing hydromorphone products when taken as intended.”

“Lastly, we anticipate achieving several milestones in 2016 in the development of KP201/IR, our acetaminophen-free hydrocodone prodrug,” Dr. Mickle concluded. “We expect to progress this program into a potential NDA filing during 2017 as we continue to advance our pipeline in a planned effort to submit at least one new NDA each year through 2019.”

Q1 2016 Financial Results:

KemPharm’s net loss for the quarter ended March 31, 2016, was \$2.9 million, or \$0.20 per basic and diluted share, compared to a net loss of \$6.0 million, or \$2.50 per basic and diluted share, for the same period in 2015. The decrease in net loss period-to-period is primarily due to a \$6.9 million increase in total other income (expense) primarily related to an increase in fair value adjustment of \$12.0 million caused by a decrease in the value of our derivative and warrant liability and an increase in interest and other income of \$0.1 million; partially offset by an increase of \$0.5 million in interest expense related to the Deerfield facility and the 2021 Notes issued during the quarter, and a loss on extinguishment of debt of \$4.7 million related to the repayment of Deerfield term note during the period. In addition, an increase in research and development costs of \$1.1 million, primarily related to increased headcount and advisory committee preparation costs, and an increase in general and administrative expenses of \$2.8 million, primarily related to increased headcount and legal and professional fees offset the increase in other income (expense) during the period.

As of March 31, 2016, cash, cash equivalents and marketable securities totaled \$111.0 million. Cash used in operations for the quarter ended March 31, 2016, was approximately \$3.9 million, consisting of the net loss of \$2.9 million, a decrease of \$2.7 million for non-cash adjustments to reconcile net loss to net cash used in operations, a decrease in accounts payable and other accrued expenses of \$0.7 million, offset by the receipt of the refund of the \$2.4 million user fee for the Apadaz NDA.

Conference Call Information:

The Company will host a conference call and live audio webcast on Thursday, May 12, 2016, at 4:30 p.m. ET, to discuss its corporate and financial results for the first quarter 2016. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 5096863

An audio webcast will be accessible via the Investor Relations section of the KemPharm website <http://investors.kempharm.com/>. An archive of the webcast will remain available for 90 days beginning at approximately 5:30 p.m. ET, on May 12, 2016.

About KemPharm:

KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of prodrugs to treat serious medical conditions through its Ligand Activated Therapy (LAT) platform technology. KemPharm utilizes its LAT platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of pain, ADHD and other CNS disorders.

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 21-E 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. These forward-looking statements include statements regarding the timing of completion of the FDA’s review of KemPharm’s NDA for Apadaz, the expected features and characteristics of KP511, the timelines surrounding potential clinical trials for KP511, and the release of any related data and the timing of the submissions of NDAs for KP511/ER, KP201/IR, or any of KemPharm’s other product candidates. These forward-looking statements are not guarantees of future actions or performance. 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 uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: KemPharm's financial resources and whether they will be sufficient to meet KemPharm's business objectives and operational requirements; results of earlier studies and trials may not be predictive of future clinical trial results; the protection and market exclusivity provided by KemPharm's intellectual property; risks related to the drug discovery and the regulatory approval process; and the impact of competitive products and technological changes. KemPharm's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning KemPharm’s business are described in additional detail in KemPharm's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and on KemPharm's other Periodic and Current Reports filed with the SEC. 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 March 31,	
	2016	2015
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	3,234	2,119
General and administrative	3,736	977
Total operating expenses	<u>6,970</u>	<u>3,096</u>
Loss from operations	<u>(6,970)</u>	<u>(3,096)</u>
Other (expense) income:		
Loss on extinguishment of debt	(4,740)	—
Interest expense related to amortization of debt issuance costs and discount	(442)	(477)
Interest expense on principal	(1,150)	(632)
Fair value adjustment	10,278	(1,762)
Interest and other income	102	—
Total other income (expense)	<u>4,048</u>	<u>(2,871)</u>
Loss before income taxes	(2,922)	(5,967)
Income tax expense	(12)	(7)
Net loss	<u>\$ (2,934)</u>	<u>\$ (5,974)</u>
Net loss per share:		
Basic and diluted	<u>\$ (0.20)</u>	<u>\$ (2.50)</u>
Weighted average common shares outstanding:		
Basic and diluted	<u>14,495,703</u>	<u>2,387,092</u>

KEMPHARM, INC.
CONDENSED BALANCE SHEETS
(In Thousands, Except Share and Par Value Amounts)

	<u>As of</u> <u>March 31,</u> <u>2016</u> <u>(unaudited)</u>	<u>As of</u> <u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 77,333	\$ 32,318
Marketable securities	33,668	19,002
Prepaid expenses and other current assets	386	2,758
Total current assets	111,387	54,078
Property and equipment, net	443	403
Other long-term assets	109	109
Total assets	<u>\$ 111,939</u>	<u>\$ 54,590</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,178	\$ 4,906
Current portion of convertible notes	1,649	1,369
Current portion of term notes	—	2,041
Current portion of capital lease obligation	18	26
Total current liabilities	5,845	8,342
Convertible notes, net	90,086	7,412
Term notes, net	—	11,118
Derivative and warrant liability	27,479	37,839
Other long-term liabilities	11	—
Total liabilities	<u>123,421</u>	<u>64,711</u>
Commitments and contingencies (Note D)		
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,498,930 shares issued and outstanding as of March 31, 2016 (unaudited); 14,490,954 shares issued and outstanding as of December 31, 2015	1	1
Additional paid-in capital	96,275	94,702
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2016 (unaudited) or December 31, 2015	—	—
Accumulated deficit	(107,758)	(104,824)
Total stockholders' deficit	<u>(11,482)</u>	<u>(10,121)</u>
Total liabilities and stockholders' deficit	<u>\$ 111,939</u>	<u>\$ 54,590</u>