
**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): March 10, 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 March 10, 2016, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter and year ended December 31, 2015, as well as information regarding a conference call to discuss these corporate and financial results, as well as provide an update on its commercial strategy for KP201/APAP. 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 Q4 and Year End 2015 Results” dated March 10, 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: March 10, 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 Q4 and Year End 2015 Results" dated March 10, 2016.



KemPharm, Inc. Reports Q4 and Year End 2015 Results

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

Recent Clinical Development & Regulatory Highlights:

- Submitted New Drug Application (NDA) under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for KP201/APAP to the U.S. Food and Drug Administration (FDA)
- Granted priority review by the FDA for the KP201/APAP NDA, with a target action date under the Prescription Drug User Fee Act (PDUFA) of June 9, 2016
- Filed Investigational New Drug (IND) application to investigate KP511, KemPharm's prodrug of hydromorphone
- Initiated development of KP746, a recently identified oral prodrug of oxymorphone

Recent Corporate and Financial Highlights:

- Expanded commercial team with the appointment of Matthew Casbon, Vice President of Marketing, Nicholas Holsman, Senior Director Commercial Strategy & Market Access, and Mike Wasyluk, Director of Product Marketing
- Announced the closing of the offering of \$86.25 million aggregate principal amount of 5.50% senior convertible notes due 2021 on February 9, 2016
- Net loss of \$0.64 per basic and diluted share for the quarter ended 12/31/2015; net loss of \$7.42 per basic and diluted share for the year ended 12/31/2015
- Cash and cash equivalents and marketable securities balance was \$51.3M at 12/31/2015, a decrease of \$7.7 million from 9/30/2015
- On a pro-forma basis, including the net proceeds from the 2021 notes offering, cash, cash equivalents and marketable securities was \$115.5 million at 12/31/2015

Coralville, IA – March 10, 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 quarter and year ended December 31, 2015.

KemPharm today also announced key additions to the Company's commercial team with the appointment of Matthew Casbon, Vice President of Marketing; Nicholas Holsman, Senior Director Commercial Strategy and Market Access; and Mike Wasyluk, Director of Product Marketing. Reporting to Tracy M. Woody, Chief Commercial Officer of KemPharm, Mr. Casbon, Mr. Holsman and Mr. Wasyluk are responsible for planning and executing the commercialization strategy for KP201/APAP and for building market awareness of the Company's franchise of prodrug product candidates.

Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm, stated, “2015 was a transformational year for KemPharm across all fronts of our business – operationally, financially and most importantly, in product development. From the completion of our initial public offering in April to the submission of the NDA for KP201/APAP in December, KemPharm achieved multiple milestones that advance our strategy of building a high-growth specialty pharmaceutical company with a franchise of proprietary prodrugs. Led by KP201/APAP, our prodrug product candidates are designed to improve one or more attributes of approved drugs, such as susceptibility to abuse, bioavailability and safety.”

Dr. Mickle continued, “2016 is poised to be an even more exciting year for KemPharm. In successive days in February, we closed an \$86.25 million debt offering, followed by notification from the FDA that the NDA for KP201/APAP was accepted, granted priority review and assigned a PDUFA date of June 9, 2016. These events favorably position KemPharm to potentially introduce KP201/APAP as the first FDA-approved immediate-release (IR), abuse-deterrent hydrocodone/APAP option for the short-term management of acute pain, potentially providing prescribers and patients with a new acute pain treatment option that may deter certain common methods of abuse while providing the same pharmacokinetic and therapeutic effect as currently available IR hydrocodone/APAP medications.”

Dr. Mickle added, “With KP201/APAP going through the regulatory review process, KemPharm is working diligently to prepare for potential commercialization of what we believe is a unique and highly differentiated product. As announced today, KemPharm’s commercial team, led by Chief Commercial Officer Tracy Woody, has grown substantially, highlighted by the additions of Matthew Casbon, Vice President of Marketing; Nicholas Holsman, Senior Director Commercial Strategy and Market Access; and Mike Wasyluk, Director of Product Marketing. Together with Tracy, Matt, Nick and Mike have spearheaded multiple initiatives to prepare for the potential commercialization of KP201/APAP, including conducting extensive research of the rapidly evolving prescription opioid market and the anticipated growth of the abuse-deterrent category.”

Dr. Mickle concluded, “While KP201/APAP is our most visible product candidate, we continue to strengthen our broader pain portfolio with the introduction of KP746, our prodrug of oxymorphone, and the recently announced IND filing for KP511, our prodrug of hydromorphone, which we plan to develop as an abuse-deterrent, extended-release (ER) medication for the treatment of moderate to severe pain. As KemPharm transitions to a commercial-ready company, we remain dedicated to maximizing the value of our entire pipeline and achieving our goal, beginning in 2017, of submitting at least one new NDA each year through 2019.”

Q4 and Year-End 2015 Financial Results:

KemPharm’s net loss for the quarter ended December 31, 2015, was \$9.2 million, or \$0.64 per basic and diluted share, compared to a net loss of \$11.8 million, or \$4.97 per basic and diluted share, for the same period in 2014. The decrease in net loss period-to-period is primarily due to a \$1.2 million decrease in research and development costs primarily related to KP201/APAP, a \$2.4 million decrease in total other expenses primarily related to a reduced increase in the fair value of our derivative and warrant liability, offset by a \$1.0 million increase in general and administrative costs associated with increased personnel-related and marketing costs due to increased headcount and pre-commercialization activities.

KemPharm’s net loss for the year ended December 31, 2015, was \$54.7 million, or \$7.42 per basic and diluted share, compared to a net loss of \$24.5 million, or \$10.27 per basic and diluted share, for the same period in 2014. The increase in net loss period-to-period is primarily due to a \$20.1 million increase in

the fair value of our derivative and warrant liability, a \$4.4 million increase in general and administrative expenses due to increased personnel and stock compensation expenses related to increased headcount and pre-commercialization activities, a \$2.0 million increase in research and development expenses related to third party research and development spending for KP415 and KP511, and an increase of \$1.8 million in interest expense and amortization of debt issuance costs and discounts, and the absence of the \$1.9 million gain on extinguishment of debt that was recognized during the same period in 2014.

As of December 31, 2015, cash, cash equivalents and marketable securities totaled \$51.3 million. On a pro forma basis, net proceeds of \$82.8 million from the 2021 notes offering, less repayment of \$18.6 million of term note indebtedness, brought KemPharm's total cash, cash equivalents and marketable securities to \$115.5 million at December 31, 2015.

Update on Commercial Activities for KP201/APAP:

Since joining the KemPharm team in February 2015, Tracy Woody has led the Company's efforts to prepare for the potential launch of KP201/APAP by building the commercial strategy and an experienced team, which includes the addition of the following executives over the last several months:

- **Matthew Casbon, Vice President of Marketing:** Mr. Casbon joined KemPharm in February 2016 as the Vice President of Marketing. Mr. Casbon most recently served as Executive Director of Marketing for Chimerix, Inc., a biopharmaceutical company. Prior to joining Chimerix, from 2010 to 2015, Mr. Casbon led the brand marketing team as the Group Brand Director, Marketing, and Senior Director of Marketing at Salix Pharmaceuticals, a specialty pharmaceutical company, and was responsible for a portfolio of 15 promoted brands that included several successful product launches and key acquisitions. From 2009 to 2010, Mr. Casbon was the Business Director, Cystic Fibrosis/Gastroenterology and Women's Health at Abbott Laboratories. From 1997 to 2009, Mr. Casbon held various roles in sales and marketing at Solvay Pharmaceuticals, including the role of Business Director, Women's Health, Gastroenterology and Cystic Fibrosis Marketing. His category experience includes work in Opioid-Induced Constipation, Gastroenterology, Liver Disease, Cystic Fibrosis, Hormone Replacement Therapy, and HIV. Mr. Casbon received his B.A. from West Chester University.
 - **Nicholas Holsman, Senior Director Commercial Strategy and Market Access:** Mr. Holsman joined KemPharm in September 2015 as Senior Director Commercial Strategy and Market Access, bringing more than 15 years of successful industry experience to the Company. Prior to joining KemPharm, Mr. Holsman spent two years at Symphony Health Solutions in the role of Managed Markets Principal advising numerous clients about the intricacies of managed care dynamics. His work there provided him exposure to different strategies utilized by his many clients and that knowledge facilitated successful product launches on the many teams with which he was involved. Prior to Symphony Health, Mr. Holsman held the position of Director of Commercial Operations at Nextwave Pharmaceuticals Inc. where he was tasked with managing the company's contract sales organization (CSO) partner and with leading the managed care strategy and commercial system integration. Prior to Nextwave, Mr. Holsman held a number of positions at Gilead Sciences focused on market access and contracting. Prior to this, Mr. Holsman also held commercial roles at CV Therapeutics and Monogram Biosciences. Mr. Holsman received a B.A. from the University of Adelaide and a B.A. from the UC Berkeley Haas Business School/Otago University, New Zealand.
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- **Mike Wasyluk, Director of Product Marketing:** Mr. Wasyluk has served as KemPharm's Director of Product Marketing since August 2015. Prior to joining KemPharm, he served as a product manager at Salix Pharmaceuticals, Inc. where he commercialized and managed multiple gastroenterological products. Prior to Salix, Mr. Wasyluk served as a product manager at Victory Pharma, a private pharmaceutical company, which marketed opioid and non-opioid pain therapies. Mr. Wasyluk's career is further highlighted by his tenures at Novartis Pharmaceuticals, where he served in multiple sales roles of increasing responsibility promoting cardiovascular therapies, and at Cephalon where he marketed pain and central nervous system (CNS) therapies. Mr. Wasyluk earned his B.S. and M.B.A. from Rutgers University.

"The FDA and other agencies are encouraging the development of prescription opioid products with abuse-deterrent features. While there are currently five FDA-approved ER opioid products with some sort of abuse-deterrent formulation, these products address less than 5% of the total prescriptions for opioids each year," said Tracy Woody. "IR hydrocodone/APAP is the most widely prescribed product within the entire opioid class with over 90 million prescriptions written in 2015, and there is currently no FDA-approved abuse-deterrent IR hydrocodone/APAP product available. We believe this represents an unmet need, and our market research shows prescribers and payors would welcome the entry of KP201/APAP to the market."

Conference Call Information:

KemPharm will host a conference call and live audio webcast today at 4:30 p.m., E.T. to discuss its corporate and financial results for the quarter and year ended December 31, 2015, as well as provide an update on its commercial strategy for KP201/APAP.

Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.); Conference ID: 64670448
- +1 (678) 509-7538 (international); Conference ID: 64670448

An audio webcast will be accessible via the Investor Relations section of the KemPharm website <http://investors.kempharm.com/>. A replay of the call will be available for 90 days beginning at approximately 5:30 p.m., ET today.

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 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 Current Report on Form 8-K (File No. 001-36913) filed with the Securities and Exchange Commission (SEC) on December 18, 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 December 31,		Twelve months ended December 31,	
	2015	2014	2015	2014
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,716	5,911	13,931	11,917
General and administrative	2,566	1,577	8,883	4,526
Total operating expenses	7,282	7,488	22,814	16,443
Loss from operations	(7,282)	(7,488)	(22,814)	(16,443)
Other expenses	(1,922)	(4,326)	(31,824)	(8,034)
Loss before income taxes	(9,204)	(11,814)	(54,638)	(24,477)
Income tax (expense) benefit	1	(27)	(26)	22
Net loss	\$ (9,203)	\$ (11,841)	\$ (54,664)	\$ (24,455)
Net loss per share:				
Basic and diluted	\$ (0.64)	\$ (4.97)	\$ (7.42)	\$ (10.27)
Weighted average common shares outstanding:				
Basic and diluted	14,443,421	2,381,041	7,368,681	2,381,041

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

	As of December 31, 2015	As of December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,318	\$ 10,255
Marketable securities	19,002	—
Prepaid expenses and other current assets	2,758	23
Total current assets	54,078	10,278
Debt issuance costs, net	1,133	1,468
Property and equipment, net	403	352
Other long-term assets	109	1,616
Total assets	\$ 55,723	\$ 13,714
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,906	\$ 3,096
Current portion of convertible notes	1,369	325
Current portion of term notes	2,041	482
Current portion of capital lease obligation	26	32
Total current liabilities	8,342	3,935
Convertible notes, net	7,865	7,235
Term notes, net	11,798	10,853
Derivative and warrant liability	37,839	15,966
Capital lease obligation, net	—	26
Total liabilities	65,844	38,015
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 1,294,000 authorized, 1,293,838 shares issued and outstanding as of December 31, 2014	—	3,343
Series B redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 829,234 shares authorized, issued and outstanding as of December 31, 2014	—	3,313
Series C redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 2,474,400 shares authorized, 2,474,122 shares issued and outstanding as of December 31, 2014	—	11,892
Series D redeemable convertible preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding as of December 31, 2015; 10,000,000 shares authorized, 967,359 shares issued and outstanding as of December 31, 2014	—	5,659
Total redeemable convertible preferred stock	—	24,207
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,490,954 shares issued and outstanding as of December 31, 2015; \$0.0001 par value, 140,000,000 shares authorized, 2,381,041 shares issued and outstanding as of December 31, 2014	1	—
Additional paid-in capital	94,702	1,652
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2015 or December 31, 2014, respectively	—	—
Accumulated deficit	(104,824)	(50,160)
Total stockholders' deficit	(10,121)	(48,508)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 55,723	\$ 13,714