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

FORM 8-K/A

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 23, 2017

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2500 Crosspark Road, Suite E126 Coralville, IA		**52241**
(Address of Principal Executive Offices)		**(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Explanatory Note

This Amendment No. 1 on Form 8-K/A is an amendment to the Current Report on Form 8-K, or the Form 8-K, of KemPharm, Inc., a Delaware corporation, or KemPharm, filed with the Securities and Exchange Commission on May 10, 2017. This Amendment No. 1 being furnished for the sole purpose of including as exhibits a corrected version of a press release and investor presentation as described in further detail in Item 2.02 below.

Item 2.02 Results of Operations and Financial Condition.

On May 22, 2017, KemPharm filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, or the Form 10-Q. KemPharm is furnishing this amendment on Form 8-K/A to the Form 8-K to correct an error which affected the amount of the non-cash fair value adjustment to the derivative and warrant liability for the three months ended March 31, 2017. This correction is reflected in the press release furnished as Exhibit 99.1 to this Amendment No. 1 to Form 8-K, or the press release, and as disclosed in the investor presentation furnished as Exhibit 99.2 to this Amendment No. 1 to Form 8-K, or the investor presentation. The error did not affect total cash and security-related amounts, which includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments, as of March 31, 2017. In addition, operating loss was unchanged.

The error required a correction of certain amounts reflected in the body of the press release, including the statement in the first bullet under the heading "Financial Highlights" which should read "Net loss of $1.11 per basic and diluted share for the quarter ended March 31, 2017" and the first paragraph under the heading "Q1 2017 Financial Results" which should read as follows:

> "KemPharm's reported net loss of $16.3 million, or $1.11 per basic and diluted share for Q1 2017, compared to net loss of $2.9 million, or $0.20 per basic and diluted share, for the same period in 2016. The increase in net loss for Q1 2017 was primarily attributable to a period-over-period change of $17.5 million in fair value adjustment caused by non-cash expense of $7.2 million for the three months ended March 31, 2017 compared to non-cash income of $10.3 million for the three months ended March 31, 2016 related to changes in the derivative and warrant liability for each period. Also contributing to the increase in net loss is an increase in loss from operations of $0.4 million and an increase in net interest expense and other items of $0.2 million. These increases in costs were partially offset by the non-recurrence in 2017 of a non-cash loss on extinguishment of debt of $4.7 million recognized during the three months ended March 31, 2016 related to the payment of a term note. Loss from operations for Q1 2017 was $7.4 million, compared to $7.0 million for the same period in 2016. The increase in loss from operations for Q1 2017 compared to the same quarter in 2016 was primarily due to an increase in research and development costs of $0.9 million with increased activity on the development programs for KP415, KP201/IR and KP511, offset by a decrease of $0.5 million in general and administrative expenses."

The error also required a correction of certain amounts disclosed in the tables at the end of the press release, including "Fair value adjustment," the corrected total of which is $(7.216 million), "Total other (expense) income," the corrected total of which is $(8.946 million), "Loss before income taxes," the corrected total of which is $(16.326 million), "Net Loss," the corrected total of which is $(16.322 million), and "Net Loss per share, basic and diluted" the corrected total of which is $(1.11) per share, in the Unaudited Condensed Statement of Operations and "Derivative and warrant liability," the corrected total of which is $11.834 million, "Total liabilities," the corrected total of which is $109.570 million, "Accumulated deficit," the corrected total of which is $(137.662 million), and "Total stockholders' deficit," the corrected total of which is $(33.929 million), in the Condensed Balance Sheets.

The error also required a correction of certain amounts reflected in the investor presentation, including, on slide 4, the statement "Net loss of $0.84 per basic and diluted share for the quarter ended 3/31/2017" should read "Net loss of $1.11 per basic and diluted share for the quarter ended 3/31/2017" and, on slide 12, the statement "Q1 net loss of $12.2M, or $0.84 per basic and diluted share, vs. Q1 2016 net loss of $2.9M, or $0.20 basic and diluted shares" should read "Q1 net loss of $16.3M, or $1.11 per basic and diluted share, vs. Q1 2016 net loss of $2.9M, or $0.20 basic and diluted shares." In addition, also on slide 12, the statement "Net loss for Q1 2017 increased primarily due to non-cash fair value adjustments to our derivative and warrant liabilities, which shifted from non-cash income of $10.3 million in Q1 2016 to a non-cash loss of $3.1 million in Q1 2017 " should read "Net loss for Q1 2017 increased primarily due to non-cash fair value adjustments to our derivative and warrant liabilities, which shifted from non-cash income of $10.3 million in Q1 2016 to a non-cash loss of $7.2 million in Q1 2017."

A copy of the corrected press release and investor presentation is furnished as Exhibits 99.1 and 99.2, respectively, to this Amendment No. 1 on Form 8-K/A.

KemPharm previously conducted a conference call to review its financial results on May 10, 2017, at 4:30 p.m. Eastern Time.

The information contained in the press release and investor presentation furnished as Exhibits 99.1 and 99.2, respectively, 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, originally dated May 10, 2017, as updated May 23, 2017.
99.2	Investor presentation, originally dated May 10, 2017, as updated May 23, 2017.

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 23, 2017

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, originally dated May 10, 2017, as updated May 23, 2017.
99.2	Investor presentation, originally dated May 10, 2017, as updated May 23, 2017.

EXHIBIT 99.1

KemPharm, Inc. Reports First Quarter 2017 Results

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

Clinical Development & Regulatory Highlights:

- Reported Positive Data from Proof-of-Concept Phase 1 Intranasal Pharmacokinetic Study of KP511
- Announced Additional U.S. Patents for KP511 and KP201/IR
- Presented Clinical Data for KP201/IR and KP511 at American Academy of Pain Medicine's Annual Meeting

Financial Highlights:

- Net loss of $1.11 per basic and diluted share for the quarter ended March 31, 2017
- Quarterly operating expense increased, as compared to Q1 2016, $0.4 million, driven primarily by increases in R&D spending
- Total cash and security-related amounts were $72.4 million at March 31, 2017, which includes cash, cash equivalents, restricted cash, marketable securities and long-term investments balance

Coralville, IA – May 10, 2017 (Updated May 23, 2017) – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today reported its corporate and financial results for the first quarter ended March 31, 2017, including an update on key clinical events involving its prodrug development pipeline.

"Since the beginning of the year, we have continued to advance our clinical programs for KP415, KP201/IR and KP511, and we believe we are now well positioned to meet the multiple clinical milestones that are anticipated throughout 2017 and into 2018," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "Additionally, we continue to pursue the FDRR process with Apadaz with a potential resolution this year."

"Over the next several months," Dr. Mickle continued, "we look forward to initiating and reporting data from multiple pharmacokinetic studies of KP415 followed by the initiation of the pivotal efficacy study in the second half of 2017. We are moving forward with our strategic initiative to expand our pharmaceutical industry footprint and monetize our Ligand Activated Therapy (LAT) prodrug platform by identifying new prodrugs for internal development and possibly discovering new prodrugs in partnership with other pharmaceutical companies. We believe that there are a number of drug products where the potential of a prodrug to improve the various properties of an active pharmaceutical ingredient offers an opportunity to increase the marketability of the parent drug."

Q1 2017 Financial Results:

KemPharm's reported net loss of $16.3 million, or $1.11 per basic and diluted share for Q1 2017, compared to net loss of $2.9 million, or $0.20 per basic and diluted share, for the same period in 2016. The increase in net loss for Q1 2017 was primarily attributable to a period-over-period change of $17.5 million in fair value adjustment caused by non-cash expense of $7.2 million for the three months ended March 31, 2017 compared to non-cash income of $10.3 million for the three months ended March 31, 2016 related to changes in the derivative and warrant liability for each period. Also contributing to the increase in net loss is an increase in loss from operations of $0.4 million and an increase in net interest expense and other items of $0.2 million. These increases in costs were partially offset by the non-recurrence in 2017 of a non-cash loss on extinguishment of debt of $4.7 million recognized during the three months ended March 31, 2016 related to the payment of a term note. Loss from operations for Q1 2017 was $7.4 million, compared to $7.0 million for the same period in 2016. The increase in loss from operations for Q1 2017 compared to the same quarter in 2016 was primarily due to an increase in research and development costs of $0.9 million with increased activity on the development programs for KP415, KP201/IR and KP511, offset by a decrease of $0.5 million in general and administrative expenses.

As of March 31, 2017, total cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments was $72.4 million, which reflected a decrease of $9.7 million compared to December 31, 2016. Based on the Company's current forecast, existing resources are expected to fund operating expenses and capital expenditure requirements through Q2 2019.

Conference Call Information:

The company will host a conference call and live audio webcast with slide presentation on Wednesday, May 10, 2017, at 4:30 p.m. ET, to discuss its corporate and financial results for the first quarter 2017. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 15162616

The live webcast with accompanying slides will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available for 90 days beginning at approximately 5:30 p.m., ET on May 10, 2017.

First Quarter Activities:

- **Reported Positive Data from Phase 1 Intranasal Pharmacokinetic Study of KP511**
  On January 9, 2017, KemPharm announced the results of its exploratory Phase 1, double-blind, single-dose, 2-treatment, 2-period, randomized, crossover study (KP511.A01) intended to assess the pharmacokinetic (PK), safety and intranasal abuse potential of KP511 Active Pharmaceutical Ingredient (API) compared to equivalent doses of hydromorphone hydrochloride (HM API). KP511 is KemPharm's investigational prodrug of hydromorphone for the treatment of pain. In this study, KP511 API showed statistically significant reduction in peak and overall hydromorphone exposure compared to HM API. The improved PK of KP511 resulted in meaningful, statistically lower scores in the exploratory pharmacodynamic (PD) measures of "Drug Liking," "Feeling High," "Overall Drug Liking" and "Take Drug Again" when compared to HM API.

- **Announced Additional U.S. Patent Protection for KP511 and KP201/IR**
  On February 23, 2017, KemPharm announced enhancements to its U.S. and global intellectual property estate governing its portfolio of prodrug product candidates. The United States Patent and Trademark Office issued two new patents: a "Composition of Matter" patent related to the KP511 family of compounds (U.S. Patent No. 9,566,343), and a "Dosage and Formulation" patent protection related to KP201 (U.S. Patent No. 9,549,923).

- **Presented Clinical Data for KP201/IR and KP511 at American Academy of Pain Medicine's Annual Meeting**
  On March 16, 2017, KemPharm announced that clinical data from two of its opioid prodrug candidates, KP511 and KP201/IR, were presented at the American Academy of Pain Medicine (AAPM) Annual Meeting. The first poster, titled, "*Oral pharmacokinetics of KP511, a prodrug of hydromorphone, relative to hydromorphone in human volunteers,*" reported the results of a Phase 1 proof-of-concept study for KP511. The second poster, titled, "*Pharmacokinetics and Abuse Potential of Benzhydrocodone, A Novel Prodrug of Hydrocodone, After Intranasal Administration in Recreational Drug Users,*" reviewed the findings of the KP201.A03 trial, which compared hydrocodone exposure following insufflation of KP201/IR vs. hydrocodone bitartrate.

About KemPharm

KemPharm is a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary 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 central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415, an extended-release prodrug of methylphenidate for the treatment of ADHD, and KP201/IR, an acetaminophen-free formulation of the company's immediate release abuse deterrent hydrocodone product candidate, KP201. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

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. These forward-looking statements include statements regarding the expected features and characteristics of KP415, KP201/IR and KP511, the expected timing of the initiation and completion of any clinical trials for the Company's product candidates and the expected timing for the reporting of data from those trials. 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; the impact of competitive products and technological changes; and the FDA approval process under the Section 505(b)(2) regulatory pathway, including without limitation any timelines for related approval. 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 year ended December 31, 2016, and KemPharm's other Periodic and Current Reports filed 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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KEMPHARM, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2017	**2016**
Revenue	$ —	$ —
Operating expenses:		
Research and development	4,114	3,234
General and administrative	3,266	3,736
Total operating expenses	7,380	6,970
Loss from operations	(7,380)	(6,970)
Other (expense) income:		
Loss on extinguishment of debt	—	(4,740)
Interest expense related to amortization of debt issuance costs and discount	(390)	(442)
Interest expense on principal	(1,441)	(1,150)
Fair value adjustment	(7,216)	10,278
Interest and other income	101	102
Total other (expense) income	(8,946)	4,048
Loss before income taxes	(16,326)	(2.922)
Income tax benefit (expense)	4	(12)
Net loss	$ (16,322)	$ (2,934)
Net loss per share:		
Basic and diluted	$ (1.11)	$ (0.20)
Weighted average number of shares of common stock outstanding:		
Basic and diluted	14,646,982	14,495,703

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

	As of March 31, 2017 (unaudited)	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 12,880	$ 16,762
Restricted cash	1,100	1,100
Marketable securities	48,243	51.003
Trade date receivables	—	5,003
Prepaid expenses and other current assets	795	489
Total current assets	63,018	74,357
Property and equipment, net	2,201	1,970
Long-term investments	10,162	8,200
Other long-term assets	260	360
Total assets	$ 75,641	$ 84,887
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,584	$ 6,444
Current portion of capital lease obligation	162	157
Other current liabilities	62	41
Total current liabilities	4,808	6,642
Convertible notes, net	91,560	91,170
Derivative and warrant liability	11,834	4,618
Other long-term liabilities	1,368	1,153
Total liabilities	109,570	103,583
Stockholders' deficit:		
Common stock, $0.0001 par value, 250,000,000 shares authorized, 14,646,982 shares issued and outstanding as of March 31, 2017 (unaudited) and December 31, 2016	1	1
Additional paid-in capital	103,732	102,643
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2017 (unaudited) and December 31, 2016	—	—
Accumulated deficit	(137,662)	(121,340)
Total stockholders' deficit	(33,929)	(18,696)
Total liabilities and stockholders' deficit	$ 75,641	$ 84,887

Exhibit 99.2

First Quarter 2017 Results

May 10, 2017 (Updated May 23, 2017)

Cautionary Note Regarding Presentation Information

This presentation contains forward-looking statements, including statements about our plans to develop and commercialize our product candidates, our planned clinical trials for our prodrug product candidates, the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including expectations about our ability to use the 505(b)(2) pathway and expedited FDA review, the clinical utility of our product candidates and our intellectual property position. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. These and other risks concerning our business are described in additional detail in our Annual Report on Form 10-K filed with the SEC on March 10, 2017, and our other Periodic and Current Reports filed with the SEC. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Further, the information contained in this presentation speaks only as the date hereof. While we may elect to update the information in this presentation in the future, we disclaim any obligation to do so except to the extent required by applicable law.

This presentation also contains 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.

First Quarter 2017 – Conference Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **Dan Cohen, M.A.L.S.** – EVP, Government & Public Relations
- **R. LaDuane Clifton, CPA** – Chief Financial Officer, Secretary & Treasurer

Q1 2017 & Recent Updates

Clinical & Regulatory

- Reported Positive Data from Phase 1 Proof-of-Concept Intranasal Pharmacokinetic Trial of KP511
- Announced Additional U.S. Patent Protection for KP511 and KP201/IR
- Presented Clinical Data for KP201/IR and KP511 at American Academy of Pain Medicine's Annual Meeting

Financial

- Net loss of $1.11 per basic and diluted share for the quarter ended 3/31/2017
- Total cash was $72.4 million at 3/31/2017, which includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments
- Existing resources expected to fund activities through Q2 2019

KemPharm Overview

- Specialty pharmaceutical company discovering and developing novel **prodrugs**
- Leveraging our **LAT Platform Technology** to improve the attributes of approved drugs in large markets
- Building a pipeline of **product candidates** for the treatment of ADHD, pain and CNS disorders
- Potentially utilizing FDA's **505(b)(2) pathway** to reduce risk and expense
- Generating long-lived **composition-of-matter** patent protection

Ligand Activated Therapy (LAT) Platform Technology

1) Select FDA-approved and widely prescribed drug for improvement

2) Chemically modify using a ligand to create a prodrug
   - Ligands – GRAS or demonstrated to be safe
   - Prodrugs generate composition-based patents

3) Following ingestion, normal human metabolic processes cleave the ligand and release the active drug

- Proprietary to KemPharm and **applicable across therapeutic areas**
- Amenable to **both immediate and extended release formulations**

KP415

Product Overview

- Extended release prodrug of methylphenidate
- Phase 1 PoC Data: Earlier d-MPH exposure followed by a slower extended release of d-MPH relative to Concerta
- Data from clinical studies suggests KP415 could allow for once-daily dosing with a potentially improved onset of action
- Branded products are being pressured by patent expirations

Development Timeline

- ✓ Results from Phase 1 PoC trial announced on Dec. 14, 2016
- Additional PK studies expected to begin in 1H 2017; final data expected 2H 2017
- Pivotal efficacy trial expected to begin in 2H 2017; data expected Q1 2018
- KP415 NDA filling expected in 2018

~$13 billion ADHD market with prescriptions growing at >5% year-over-year

Source: Symphony Health Solutions, PHAST Prescription Monthly, 2012-2016

KP201/IR (APAP-free)

Product Overview

- IR formulation of benzhydrocodone combined with an aversive formulation
- Potentially the first IR hydrocodone-related product without APAP in the U.S.
- Fast Track designation
- KP201 Intranasal PK Trial (A03) already completed (n=51):
  - Significantly lower drug liking
  - 36% decrease in KP201 Cmax
  - KP201 Tmax delayed by one hour

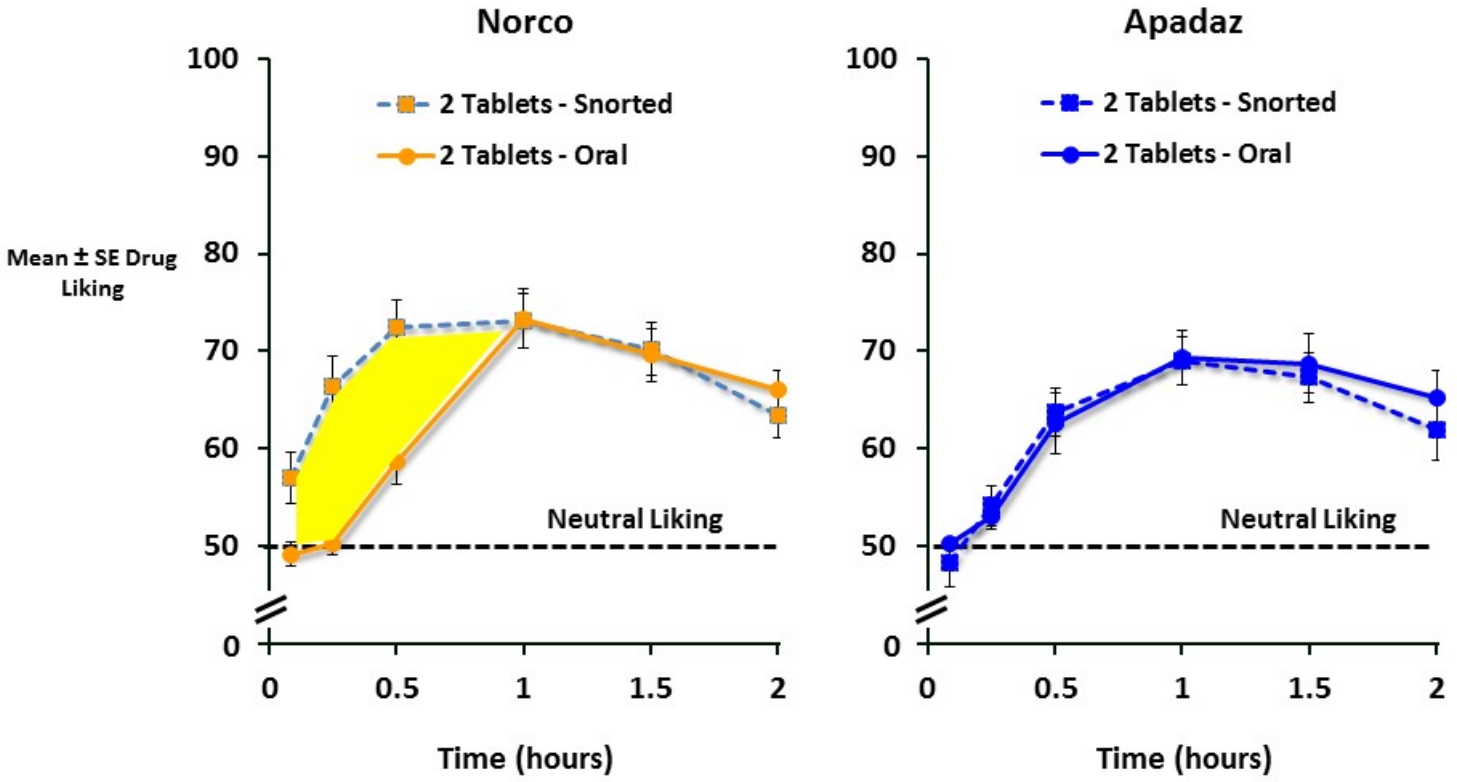
Development Timeline

- ✓ KP201/IR IND accepted by FDA on Nov. 29, 2016
- Human clinical trials of KP201/IR expected to begin in 2017; IN HAL study data projected late 2017
- KP201/IR NDA anticipated to be filed in 2018
- Priority Review expected

Formal Dispute Resolution Request (FDRR) Update

- KemPharm filed an appeal of the CRL for Apadaz™ through the initiation of the FDRR process (announced on Nov. 3, 2016)
- FDRR process is designed to provide pathway by which applicants seek to resolve scientific and/or medical policy disputes that cannot be resolved at the Division level within the FDA
- During the FDRR process, the FDA typically requests that companies not comment. The next announcement will be the final determination of the FDRR.

Norco vs. Apadaz – Drug Liking



Study A02: Intranasal HAP Study (N=42)

KP511/ER and KP511/IR

Product Overview

- Prodrug of hydromorphone
- Being developed as ER and IR formulations
- Demonstrated comparable hydromorphone exposure vs. equimolar dose of Dilaudid™ in oral human proof-of-concept trial
- Phase 1 Intranasal Data: Demonstrated statistically significant PK and PD differences of abuse potential
- Limited oral bioavailability at high doses observed in preclinical studies (potential overdose protection)

Development Timeline

- ✓ Data from intranasal HAL studies of KP511 API announced Jan. 9, 2017
- Investigation anticipated into KP511's potential to limit oral abuse and/or overdose and improve or reduce opioid-induced constipation (OIC)
- KP511/ER and KP511/IR NDAs estimated to be filed in 2019
- Priority Review expected

Q1 2017 Financial Update

- Q1 2017 net loss of $16.3M, or $1.11 per basic and diluted share, vs. Q1 2016 net loss of $2.9M, or $0.20 per basic and diluted share

  Net loss for Q1 2017 increased primarily due to non-cash fair value adjustments to our derivative and warrant liabilities, which shifted from non-cash income of $10.3 million in Q1 2016 to a non-cash loss of $7.2 million in Q1 2017.

  Loss from operations increased to $7.4M in Q1 2017, as compared to $7.0M in Q1 2016, which was driven by an increase in R&D spending of $0.9M on the development programs for KP415, KP201/IR and KP511, offset by a reduction in G&A of $0.5M.

- Total cash of $72.4M as of 3/31/2017, a decrease of $9.7M vs. 12/31/2016
  (includes cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments)

  Existing resources expected to meet operating and capital expenditure requirements through Q2 2019

KemPharm Expected Milestones

	Product	Event
2017	KP415	Initiate Additional PK Studies (1H)
	KP415	Report Additional PK Data (2H)
	KP415	Initiate Pivotal Efficacy Trial (2H)
	KP201/IR	Human Clinical Trial Initiation (Mid)
	KP201/IR	Intranasal HAL Study Data (2H)
2018	KP415	Pivotal Efficacy Trial Results
	KP415	NDA Submission
	KP201/IR	NDA Submission with Priority Review
2019	KP511/ER & KP511/IR	NDA Submissions with Priority Review

KemPharm

First Quarter 2017 Results

May 10, 2017 (Updated May 23, 2017)