
**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): November 9, 2017

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.)

2500 Crosspark Road, Suite E126
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))

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.

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2017, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its corporate and financial results for the quarter ended September 30, 2017, as well as information regarding a conference call and live webcast presentation to discuss these corporate and financial results. A copy of the press release and presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release titled “KemPharm Reports Third Quarter 2017 Results and Provides Corporate Update” dated November 9, 2017.</u>
99.2	<u>Presentation titled "Third Quarter 2017 Results" dated November 9, 2017.</u>

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: November 9, 2017

By: /s/ R. LaDuane Clifton

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer



KemPharm Reports Third Quarter 2017 Results and Provides Corporate Update

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

Development & Regulatory Highlights:

- Filed IND for KP484, A Super-Extended Release ADHD Methylphenidate Prodrug Product Candidate
 - KP484 IND Review Completed by FDA; Cleared to Proceed to Clinical Studies
- Announced FDRR Process Completion and Resubmission of the Apadaz™ NDA
 - FDA Has Assigned a PDUFA Action Date of February 23, 2018
- Entered into Licensing and Assignment Agreement with Genco Sciences to Develop a Prodrug-Based Therapy for Potential Rare Pediatric Indications of Tourette's Syndrome with ADHD
- Announced Preliminary Pharmacokinetic Phase I Trial Results for KP415

Corporate & Financial Highlights:

- Net loss of \$0.68 per basic and diluted share for the quarter ended September 30, 2017
- Quarterly operating expenses decreased \$0.8 million as compared to Q3 2016
- Total cash and security-related amounts were \$55.6 million at September 30, 2017; based on current forecast, existing resources expected to fund operating requirements through Q2 2019

Coralville, IA – November 9, 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 third quarter ended September 30, 2017, including an update on development and regulatory events involving its prodrug development pipeline.

“We continued to reach key milestones for our company during the third quarter that we believe, collectively, showcase the value potential of our prodrug pipeline and our Ligand Activated Therapy (LAT™) discovery platform,” said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. “During the quarter, we filed the Investigational New Drug (IND) application for KP484, our super-extended release prodrug for the treatment of attention deficit hyperactivity disorder (ADHD), and last week, we were pleased to report that the FDA completed its review of the KP484 IND application, enabling us to proceed to the clinic. This advancement, coupled with the ongoing development of KP415, our lead ADHD prodrug candidate, positions KemPharm to potentially have two late-stage product candidates designed to address important unmet treatment needs in ADHD.”

“The third quarter was also highlighted by the completion of the Formal Dispute Resolution Request (FDRR) process with the U.S. Food and Drug Administration (FDA) for Apadaz™ (benzhydrocodone and acetaminophen),” Dr. Mickle continued. “Initiated approximately a year ago, the FDRR process provided us an opportunity to discuss appropriate labeling language for Apadaz™. Based on the discussions, we replied to the June 2016 Complete Response Letter from the FDA by submitting an amended Apadaz™ New Drug Application (NDA), for which the FDA assigned a Prescription Drug User Fee Act (PDUFA) date of February 23, 2018.”

“Additionally, we entered into a technology licensing and assignment agreement with Genco Sciences with the goal of building on their technology to develop a new prodrug product for the treatment of pediatric Tourette’s syndrome when accompanied by ADHD,” Dr. Mickle continued. “Although still in discovery phase, we are very excited by the opportunity to harness our LAT™ prodrug discovery platform to potentially develop a new product candidate for an orphan-drug area. This agreement is the first of what we hope will be replicated as a model for our strategy to leverage our LAT™ to potentially enhance the performance of an active pharmaceutical ingredient and increase the marketability of the parent drug.”

“We anticipate that the fourth quarter and early 2018 will be a very active period for KemPharm. We anticipate multiple clinical and regulatory milestone announcements, including initiating the pivotal efficacy study for KP415, completing the combined intravenous (IV) human abuse liability study for KP415 and KP484, and, as noted previously, the PDUFA decision for Apadaz™ in February,” Dr. Mickle concluded.

Q3 2017 Financial Results:

KemPharm’s reported net loss was \$10.0 million, or \$0.68 per basic and diluted share, for the three months ended September 30, 2017, compared to net loss of \$13.4 million, or \$0.92 per basic and diluted share, for the same period in 2016. Net loss for the Q3 2017 was driven primarily by a loss from operations of \$9.6 million, and net interest expense and other items of \$1.7 million; these expenses were partially offset by non-cash fair value adjustment income of \$1.3 million. Loss from operations decreased \$0.8 million from \$10.4 million in Q3 2016 to \$9.6 million in Q3 2017. The decrease in loss from operations for Q3 2017 compared to the same quarter in 2016 was primarily due to severance expense recognized in Q3 2016 of \$3.0 million which did not recur in Q3 2017. This decrease was partially offset by increased research and development and general and administrative spending of \$2.0 million and \$0.2 million, respectively, period over period.

As of September 30, 2017, total cash and security-related amounts, which is comprised of cash, cash equivalents, restricted cash, marketable securities, trade date receivables and long-term investments, was \$55.6 million, which reflected a decrease of \$10.2 million compared to June 30, 2017. 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 Thursday, November 9, 2017, at 4:30 p.m. ET, to discuss its corporate and financial results for the third 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: 3698227

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 5:00 p.m., ET on November 9, 2017.

Recent and Third Quarter 2017 Activities:

- **Entered into Licensing and Assignment Agreement with Genco Sciences to Develop Prodrug-Based Therapy for Potential Rare Pediatric Indications of Tourette's Syndrome with ADHD**

On October 4, 2017, KemPharm entered into a technology licensing and assignment agreement with Genco Sciences, LLC (Genco) whereby KemPharm anticipates utilizing Genco's early research-stage proprietary nano-particulate amphetamine technology to devise a unique prodrug to be developed as a treatment for pediatric Tourette's syndrome when accompanied by ADHD. Under terms of the agreement, KemPharm will be responsible for financing and managing all product development.

- **Filed IND for KP484 for the Treatment of ADHD, An Investigational Prodrug of Methylphenidate**

On September 20, 2017, KemPharm announced that it filed an IND application with the FDA to begin human clinical trials of KP484, the Company's prodrug product candidate of "super-extended" release methylphenidate for the treatment of ADHD. KemPharm's IND proposal is to develop KP484 along a similar clinical trial pathway as KP415, with efficacy studies of KP484 expected to initiate in 2018.

- **Announced FDRR Process Completion and Resubmission of the Apadaz™ NDA**

On Sept. 19, 2017, KemPharm announced completion of the FDRR process with the FDA for Apadaz (benzhydrocodone and acetaminophen). Based on the FDRR discussions, KemPharm replied to the CRL by submitting an amended Apadaz NDA. The FDA notified KemPharm with the determination that the resubmitted NDA application is complete and assigned February 23, 2018, as the expected date by which an approval decision will be determined.

- **Announced Preliminary Pharmacokinetic Phase I Trial Results for KP415**

On August 10, 2017, KemPharm announced preliminary results for KP415.109, our proposed co-formulation of our proprietary extended release (ER) KP415 d-methylphenidate prodrug together with immediate release (IR) d-MPH, demonstrated expected PK parameters in this Phase I trial and is now being readied for further development in a safety and efficacy clinical trial later this year. This Phase I trial was designed to assess the relative pharmacokinetics (PK) of three different formulations of KP415 vs. a methylphenidate-containing comparator product (Concerta®) at both single and multiple dose conditions. KP415 is KemPharm's co-lead ADHD product candidate.

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 proprietary LAT™ (Ligand Activated Therapy) platform technology. KemPharm utilizes its proprietary LAT™ platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of ADHD, pain and other central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release profiles for the treatment of ADHD. In addition, the company is advancing Apadaz™, an immediate-release, abuse-deterrent hydrocodone/acetaminophen combination product candidate, 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 any product candidates developed under the Genco license agreement, KP415, KP484, Apadaz™ and KemPharm’s other product candidates, the expected timing of the initiation and completion of any clinical trials for KemPharm’s product candidates, the expected timing and outcome from the resubmission of KemPharm’s Apadaz NDA with the FDA, and KemPharm’s current forecast that existing resources are expected to fund operating expenses and capital expenditure requirements through Q2 2019. 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 September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	6,293	4,287	15,057	12,509
General and administrative	3,319	3,104	10,159	11,127
Severance expense	—	3,010	—	3,010
Total operating expenses	<u>9,612</u>	<u>10,401</u>	<u>25,216</u>	<u>26,646</u>
Loss from operations	<u>(9,612)</u>	<u>(10,401)</u>	<u>(25,216)</u>	<u>(26,646)</u>
Other (expense) income:				
Loss on extinguishment of debt	—	—	—	(4,740)
Interest expense related to amortization of debt issuance costs and discount	(391)	(390)	(1,171)	(1,225)
Interest expense on principal	(1,448)	(1,441)	(4,332)	(4,066)
Fair value adjustment	1,312	(1,299)	(2,381)	29,742
Interest and other income, net	154	98	268	344
Total other (expense) income	<u>(373)</u>	<u>(3,032)</u>	<u>(7,616)</u>	<u>20,055</u>
Loss before income taxes	<u>(9,985)</u>	<u>(13,433)</u>	<u>(32,832)</u>	<u>(6,591)</u>
Income tax benefit	4	19	12	11
Net loss	<u>\$ (9,981)</u>	<u>\$ (13,414)</u>	<u>\$ (32,820)</u>	<u>\$ (6,580)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.92)</u>	<u>\$ (2.24)</u>	<u>\$ (0.45)</u>
Weighted average number of shares of common stock outstanding:				
Basic and diluted	<u>14,657,430</u>	<u>14,646,982</u>	<u>14,651,371</u>	<u>14,580,289</u>

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

	As of September 30, 2017 <u>(unaudited)</u>	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,829	\$ 16,762
Restricted cash	1,100	1,100
Marketable securities	37,412	51,003
Trade date receivables	2,503	5,003
Prepaid expenses and other current assets	1,354	489
Total current assets	<u>50,198</u>	<u>74,357</u>
Property and equipment, net	2,086	1,970
Long-term investments	6,717	8,200
Other long-term assets	313	360
Total assets	<u>\$ 59,314</u>	<u>\$ 84,887</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,355	\$ 6,444
Current portion of capital lease obligation	180	157
Other current liabilities	112	41
Total current liabilities	<u>6,647</u>	<u>6,642</u>
Convertible notes, net	92,341	91,170
Derivative and warrant liability	6,999	4,618
Other long-term liabilities	1,427	1,153
Total liabilities	<u>107,414</u>	<u>103,583</u>
Stockholders' deficit:		
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 14,657,430 shares issued and outstanding as of September 30, 2017 (unaudited); 14,646,982 shares issued and outstanding as of December 31, 2016	1	1
Additional paid-in capital	106,059	102,643
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2017 (unaudited) and December 31, 2016	—	—
Accumulated deficit	<u>(154,160)</u>	<u>(121,340)</u>
Total stockholders' deficit	<u>(48,100)</u>	<u>(18,696)</u>
Total liabilities and stockholders' deficit	<u>\$ 59,314</u>	<u>\$ 84,887</u>



KemPharm

Third Quarter 2017 Results

November 9, 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 Quarterly Report on Form 10-Q filed with the SEC on August 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.



Third Quarter 2017 – Conference Call Participants

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



Q3 2017 & Recent Updates

Development and Regulatory

- Filed IND for KP484, a Super-Extended Release ADHD Methylphenidate Prodrug Product Candidate
- Announced FDRR Process Completion and Resubmission of the Apadaz™ NDA
 - *FDA Has Assigned a PDUFA Action Date of February 23, 2018*
- Entered into Licensing and Assignment Agreement with Genco Sciences to Develop Prodrug-Based Therapy for Potential Rare Pediatric Indications of Tourette's Syndrome with ADHD

Financial

- Net loss of \$0.68 per basic and diluted share for the quarter ended 9/30/2017
- Total cash was \$55.6 million at 9/30/2017, 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**
- Building a pipeline of **prodrug product candidates** for the treatment of ADHD, pain and CNS disorders
- Leveraging our **LAT™ Platform Technology** to improve the attributes of approved drugs in large markets
 - 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



ADHD Prodrug Product Pipeline – Addressing Unmet Needs

KP415 – ADHD Product Candidate for Fast Onset and Longer Total Duration

- Extended release product candidate
- Prodrug of d-MPH co-formulated with IR d-MPH
- Positive PK data announced Q2
- Pivotal efficacy trial expected to begin in 2H 2017; data expected 1H 2018
- Human abuse liability clinical data in 2018 – IV, oral and IN
- KP415 NDA filing expected as early as 2018

KP484 – ADHD Product Candidate with Super Extended Release Properties

- Super-extended release product candidate
- Prodrug of d-MPH
- Initial data suggest long-acting characteristics similar to Shire's MYDAYIS™ (amphetamine-based)
- IND filed Sept. 30
- Clinical program initiated under KP415 IND; expect to benefit from KP415's development program
- Human abuse liability clinical data in 2018 – IV, oral and IN
- Potential NDA as early as 2019



ADHD Market Dynamics Support Prodrug Portfolio

KP415

- In 2016, the branded ADHD market was ~\$6.4B and more than 95% of these branded products are extended release¹
- Prescribers estimate that MPH is given as preferred first line of therapy for children under 13 approximately 60% of the time
- Prescribers see the following key advantages
 - Duration of action (60%)
 - Lower abuse potential (52%)
 - Early onset of action (43%)
- ✓ If approved, KP415 has the potential to be one of the first differentiated MPH products launched into the ADHD market in some time

KP484

- Approximately 10.5 million adults have ADHD^{1,2}
- Adults are now the largest part of the ADHD market, comprising 53% of total TRx¹
 - However, last 7 new ADHD products launched have been pediatric focused
- Vyvanse™ averaging 22% YoY growth in adult market since 2009¹
- Mydayis™ recently approved as a super long acting AXR in the amphetamine space
- ✓ If approved, KP484 would launch into the high growth adult ADHD market
 - Potential for additional indications beyond ADHD



LAT™ - New Prodrug Product Development Partnering

Strategy

- Harness our proprietary LAT™ Platform Technology by partnering with other companies that could benefit from KemPharm's prodrug discovery and development capabilities
- Partner benefits could include new products, product improvements and/or life-cycle extension opportunities base on potential:
 - ✓ Creation of new, long-lived IP protection
 - ✓ Modification of pharmacokinetic profile
 - ✓ Targeted tissue/organ delivery
 - ✓ Delivery of active metabolites
 - ✓ Modification of physicochemical or synthetic properties
 - ✓ Modifications in metabolism
 - ✓ Improved side effect profile

Genco Sciences Agreement

- Develop prodrug-based therapy for potential rare pediatric indications of Tourette's syndrome with ADHD
- KemPharm responsible for financing and managing all product development
- KemPharm owns all intellectual property and any commercial product developed as a result of this agreement
- Genco eligible to receive certain milestone and royalty-based or value share payments



Apadaz – FDRR Completion & NDA Resubmission Timeline

Product Overview

- IR opioid fixed-dose combination product comprised of 6.67 mg benzhydrocodone HCl (a prodrug of hydrocodone equivalent to 7.5 mg hydrocodone bitartrate) and 325 mg APAP
- Molecular-based abuse-deterrent technology
- Potential valuable properties based on clinical development program include
 - ✓ Reduced hydrocodone C_{max}, reduced early systemic hydrocodone exposure and delayed hydrocodone T_{max} for IN Apadaz™ vs. IN Norco™
 - ✓ Delayed Drug Liking for IN Apadaz™ vs. IN Norco™
 - ✓ Highly tamper resistant vs. Norco

FDRR and NDA Update

- FDRR process completed in line with management's expectations
- FDA acknowledged receipt of Apadaz™ NDA resubmission on August 23, 2017
- Items included in NDA resubmission
 - ✓ Revised label
 - ✓ Updated tampering data
 - ✓ Updated abuse liability assessment
 - ✓ Updated CMC information to include blister packaging (18-tablet pack, comprising a 3-day prescription)
- Apadaz™ NDA resubmission deemed complete and considered a Class 2 response by FDA
- FDA has assigned Apadaz™ a PDUFA date of February 23, 2018



KemPharm Product Candidates

Product	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD				
KP415	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2018
KP484	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2019
TBD (Genco)	TBD	Discovery	Candidate Selection	TBD
PAIN				
Apadaz™	Hydrocodone/APAP	NDA Resubmitted	PDUFA (2/23/18)	Completed
KP201/IR	Hydrocodone	Clinical	IN HAL Data	2018 Priority Review
KP511/IR	Hydromorphone	Clinical	HAL and BE Data	2019 Priority Review
KP511/ER	Hydromorphone	Clinical	POC in ER Formulation	2019 Priority Review
KP606/IR	Oxycodone	Preclinical	Preclinical Development	TBD
KP746	Oxymorphone	Preclinical	Preclinical Development	TBD
CNS				
KP303	Quetiapine	Preclinical	Preclinical Development	TBD



Financial Update – Q3 2017 Results

- Q3 2017 net loss of \$10.0M, or \$0.68 per basic and diluted share, vs. Q3 2016 net loss of \$13.4M, or \$0.92 per basic and diluted share

Net loss for Q3 2017 was primarily due to loss from operations of \$9.6 million and net interest expense and other items of \$1.7 million; offset by non-cash fair value adjustment income of \$1.3 million.

Loss from operations decreased to \$9.6M in Q3 2017, as compared to \$10.4M in Q3 2016, which was primarily driven by severance expense recognized in Q3 2016 of \$3.0 million which did not recur in Q3 2017. This decrease was partially offset by increased research and development and general and administrative spending of \$2.0 million and \$0.2 million, respectively, period over period.

- Total cash of \$55.6M as of 9/30/2017, a decrease of \$10.2M vs. 6/30/2017 (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	Apadaz	FDRR Resolution and NDA Resubmission ✓
	KP484	IND Filing (3Q) ✓
	KP415	Initiate Pivotal Efficacy Trial (2H)
2018	KP415 / KP484	IV Human Abuse Liability (HAL) Data
	Apadaz	PDUFA Date – 02/23/2018
	KP415	Pivotal Efficacy Trial Results
	KP484	Initiate Efficacy Studies
	KP415 / KP484	Oral and IN HAL Data
2019	KP415	NDA Submission
	KP484	Pivotal Efficacy Trial Results
	KP484	NDA Submission





KemPharm

Third Quarter 2017 Results

November 9, 2017



Slide 7: KP415 and KP484 Market Data Sources

1. Symphony Health, PHAST 2011-2016
2. Ronald C. Kessler et al. (April 2006). The Prevalence and Correlates of Adult ADHD in the United States: Results From the National Comorbidity Survey Replication, *American Journal of Psychiatry* 163(5):71

