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): June 28, 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. ☒

Item 7.01 Regulation FD Disclosure.

On June 28, 2017, KemPharm, Inc., or the Company, issued a press release announcing two significant advances involving its prodrug development pipeline for the treatment of attention deficit hyperactivity disorder, or ADHD. These advances include the development of a new prodrug product candidate of d-threo-methylphenidate, KP484, for ADHD indications that may benefit from a super-extended duration of treatment and the successful completion of an End-of-Phase 1 meeting with the U.S. Food and Drug Administration, or FDA, for KP415. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Also on June 28, 2017, the Company conducted a conference call and live audio webcast to discuss these matters. A copy of the slide presentation used in connection with this conference call is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 and the slide presentation furnished as Exhibit 99.2 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 the Company's filings under the Securities Act of 1933, as amended, or the Securities Act, 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.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. 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 and KP484, and the anticipated timelines for any Investigational New Drug application or New Drug Application submission or the availability of clinical trial results. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company 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: the Company's financial resources and whether they will be sufficient to meet the Company'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 the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; the impact of competitive products and technological changes; obligations to third parties regarding the potential commercialization or sale of KP415 or KP484; and the FDA approval process, including without limitation any timelines for related approval. The Company'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 the Company's business are described in additional detail in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2017, and the Company's other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Strengthens ADHD Prodrug Pipeline with Development of KP484, A New, Super-Extended Release ADHD Methylphenidate Product Candidate” dated June 28, 2017.
99.2	Presentation titled "ADHD Prodrug Pipeline Update" dated June 28, 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: June 28, 2017

By: /s/ Timothy J. Sangiovanni
Timothy J. Sangiovanni, CPA
Vice President, Corporate Controller

EXHIBIT INDEX

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EXHIBIT 99.1

KemPharm Strengthens ADHD Prodrug Pipeline with Development of KP484, A New, Super-Extended Release ADHD Methylphenidate Product Candidate

KP415 End-of-Phase 1 Meeting with FDA Affirms KemPharm's Development Plan and Potential NDA Submission as early as late 2018

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

Coralville, IA – June 28, 2017 – KemPharm, Inc. (NASDAQ: KMPH), a clinical-stage specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced two significant advances involving its prodrug development pipeline for the treatment of attention deficit hyperactivity disorder (ADHD). These advances include the development of a new prodrug product candidate of d-threo-methylphenidate (d-MPH), KP484, for ADHD indications that may benefit from a super-extended duration of treatment and the successful completion of an End-of-Phase 1 (EOP1) meeting with the U.S. Food and Drug Administration (FDA) for KP415.

KP484 – Prodrug of d-MPH for Super-Extended Duration Treatment of ADHD
KP484 is KemPharm's newly developed prodrug product candidate for a super-extended release (SER) d-MPH being designed for the treatment of ADHD in patients that respond best when a long duration of therapy beyond both KP415 and all current methylphenidate treatments is required. The new therapeutic application was developed during a data analysis of the KP415 Phase 1 study, in which KemPharm observed that the prodrug molecule demonstrated an ability to produce a longer duration release of d-MPH relative to comparator products available on the market today. As a result, KemPharm is now planning to initiate development of KP484 and anticipates filing an Investigational New Drug (IND) application for KP484 as early as the third quarter of 2017. KemPharm expects to leverage data from certain clinical and nonclinical trials of KP415 to expedite the development of KP484. KemPharm believes that this may enable it to realize key cost and R&D efficiencies and target a New Drug Application (NDA) submission as soon as 2019.

KP415 – Prodrug of d-MPH for Treatment of ADHD with Early On-set and Better Total Duration
KP415 is KemPharm's extended release (ER) d-MPH prodrug product candidate designed for the treatment of ADHD with patients that could benefit from both earlier onset as well as better total duration of effect. As previously indicated, KemPharm held an EOP1 meeting with the FDA to discuss the data from the Phase 1 proof-of-concept clinical trial of KP415 (KP415.101), additional nonclinical and manufacturing data sets, and the proposed clinical and nonclinical programs required for eventual submission of an NDA for KP415. Additionally, KemPharm and the FDA discussed the proposed commercial formulation of KP415, which KemPharm plans to develop with a layer of methylphenidate to potentially support a superior early onset profile. Based on the feedback from the FDA, KemPharm believes that its ongoing and anticipated research of KP415, including the pivotal efficacy trial, which KemPharm plans to initiate in the second half of 2017, remains on schedule and in alignment with an NDA submission as soon as late 2018. KemPharm also anticipates that it will initiate a human abuse liability (HAL) program of KP415 beginning in the second half of 2017 to assess the potential for the prodrug to deter intranasal, intravenous and oral abuse. KemPharm expects data from the HAL program and the ongoing pharmacokinetic (PK) studies will be available in the second half of 2017 and early 2018. KemPharm plans to utilize the data from both studies in the development KP484, as well.

"We now believe KemPharm's ADHD prodrug portfolio is the company's most valuable asset. In our view, the advances that we have made with KP415 and our newly developed product candidate for a super extended treatment, KP484, further support this belief," stated Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "We continue to view KP415 as our highest value product candidate, and we are excited to now take this prodrug to the next phase of its development. Since our quarterly update in May, we have initiated several pharmacokinetic studies of KP415 with data from these studies expected during the second half of 2017 and in early 2018. Now, following the End-of-Phase 1 meeting with the FDA, we are prepared to develop the commercial formulation of KP415 and initiate the pivotal efficacy study and human abuse liability program for KP415 in the second half of 2017; all pointing towards an NDA submission for KP415 as soon as late 2018."

"The success of our KP415 program is now heightened by the development of a new product we are designating as KP484, which we are planning to develop for patients that require a product that provides a much longer duration of treatment for their ADHD," Dr. Mickle continued. "In contrast to Shire's recently approved amphetamine-based MYDAYIS™ for extended duration of treatment for ADHD, initial clinical data on KP484 suggest our new methylphenidate product could offer substantially longer duration when compare to other methylphenidate ADHD drugs which is clearly an unmet need in treatment with methylphenidate. Given this, we have now activated the development program for KP484 with our first milestone being an IND filing in the third quarter."

"We believe physicians need products, such as KP415 and KP484, which are designed to provide solutions for their patients' individual needs, recognizing that many may respond differently to different treatments. Thus, it is important for patients to have multiple treatment options," Dr. Mickle concluded. "For example, some patients need milder therapies such as a methylphenidate-based option that may be just as effective and have fewer side effects when compared to amphetamine-based products."

Conference Call Information:

The company will host a conference call and live audio webcast with slide presentation today, June 28, 2017, at 4:30 p.m. ET. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 45888929

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 following the call.

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 LAT™ (Ligand Activated Therapy) 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 and KP484, and the anticipated timelines for any IND or NDA submission or the availability of clinical trial results. 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; obligations to third parties regarding the potential commercialization or sale of KP415 or KP484; and the FDA approval process, 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 Quarterly Report on Form 10-Q for the period ended March 31, 2017, 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
ADHD Prodrug Pipeline Update
June 28, 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 the expected features and characteristics of our product candidates, the clinical utility of our product candidates, the anticipated timelines for any submissions to the FDA or the availability of clinical trial results 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.

Extending ADHD Prodrug Pipeline & Value Potential

- ✓ **Completed End-of-Phase 1 Meeting with FDA for KP415**
  - ADHD treatment focused on addressing unmet need with a faster onset of efficacy with a longer total duration than current methylphenidate treatment options
  - KP415 clinical program affirmed by FDA
  - Should data be favorable, clinical and PK Studies may be sufficient for as early as late 2018 NDA submission
- ✓ **Announced Development of New ADHD Product Candidate – KP484**
  - ADHD product candidate focused on addressing unmet need with potentially longer duration than other current methylphenidate treatments, including KP415
  - KemPharm intends to file IND for KP484 as early as 3Q 2017; NDA submission targeted as early as 2019
  - Development pathway may benefit from KP415 research

ADHD Prodrug Product Pipeline – Addressing Unmet Needs

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

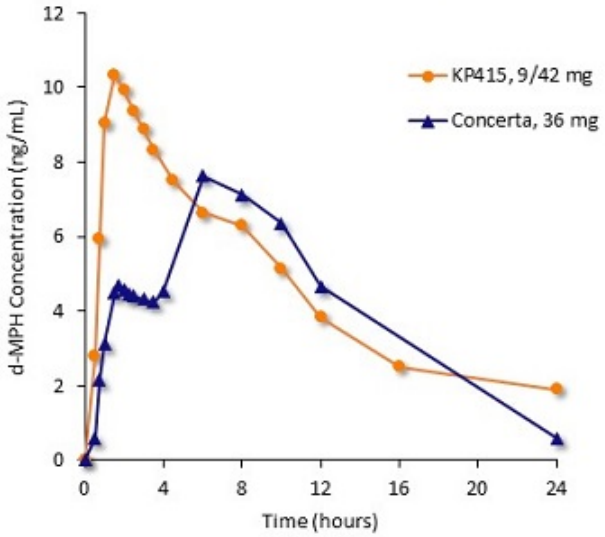
- Extended release prodrug of d-threo-methylphenidate (d-MPH)
- Phase 1 PoC data complete
- Additional PK studies underway; final PK study data anticipated in 2H 2017 through early 2018
- Human abuse liability clinical data by year end (IV) as well as in 2018 (oral and IN)
- Pivotal efficacy trial expected to begin in 2H 2017; data expected 1H 2018
- KP415 NDA filing expected as early as late 2018

KP484 – ADHD Product Candidate with Super Extended Release Properties

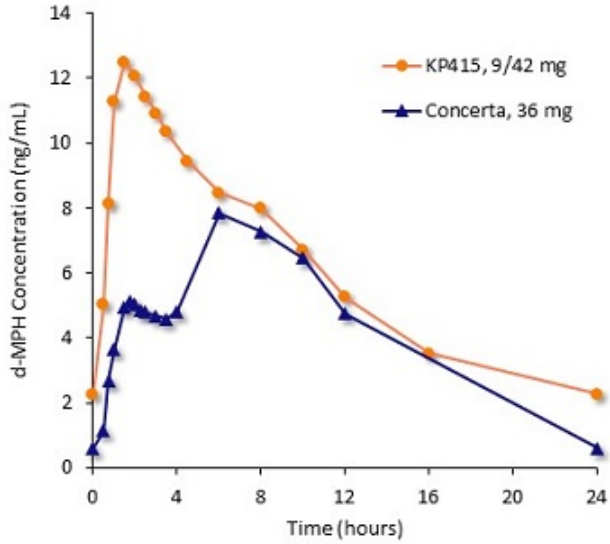
- Newly developed, super extended release prodrug of d-MPH
- Initial data suggest long acting characteristics similar to Shire's MYDAYIS™ (amphetamine-based)
- Human abuse liability clinical data as early as year end (IV) and early 2018 (oral and IN)
- IND expected to be filed as early as 3Q 2017
- Clinical program initiated under KP415 IND; expect benefit from KP415's development program
- Potential NDA as early as 2019

Predicted Oral PK Data – KP415

Commercial KP415 – Predicted PK, Single Dose



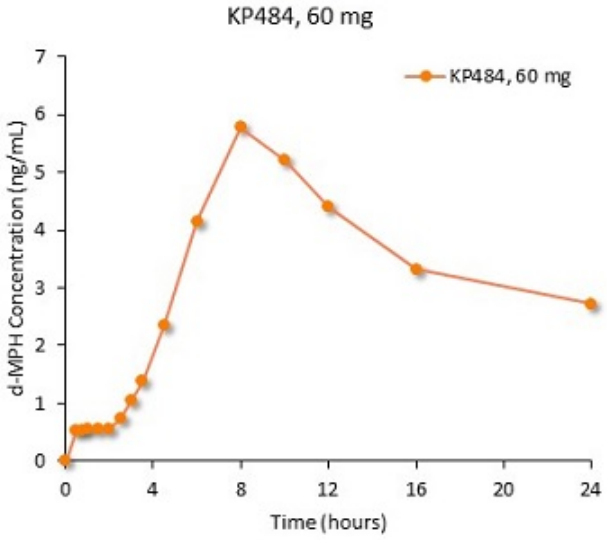
Commercial KP415 – Predicted Oral PK, Steady State



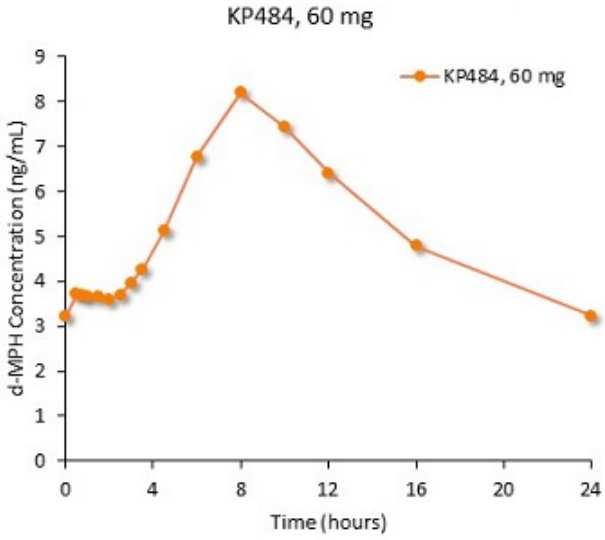
Note: Steady-state plasma concentrations were modeled based on single-dose data.

Oral Pharmacokinetic Data – KP484

KP484 – Oral PK, Single Dose



KP484 – Predicted Oral PK, Steady State



Note: Steady-state plasma concentrations were modeled based on single-dose data.

Completed Clinical Studies of KP484

- KP484 Clinical Data to Date
  - Single dose oral bioavailability and dose proportionality of 20, 40, and 60 mg in capsules
  - Urinary excretion study following single oral dose of 6 and 60 mg administered as oral liquids
  - Effect of food on the oral bioavailability and pharmacokinetics with a 60 mg capsule

ADHD and ER Methylphenidate Market

- ~$13 billion ADHD market with prescriptions growing at >5% year-over-year
- Methylphenidate accounted for approximately 19.8 million TRx's and $3.8 billion in sales in 2016
- KemPharm believes ADHD key opinion leaders have significant interest in an ER methylphenidate product with:
  - Earlier onset (KP415)
  - Improved duration of action (KP415 & KP484)
  - Abuse-deterrent properties/Lower abuse potential (KP415 & KP484)
- Branded products are being pressured by patent expirations
  - Vyvanse™ is the branded market share leader and loses patent exclusivity in 2024
  - Concerta™, Adderall ™, Focalin ™ are all brands which are off patent

Source: Symphony Health, PHAST 2016

KP415: ADHD Market Dynamics

- Although the ADHD market has become more genericized, many generics are priced closely to their branded comparator's. In 2016, the branded ADHD market was ~$6.4B(1)
  - >95% of these branded products are Extended Release (1)
- In the prior 4 years, there have been seven (7) product launches based on delivery mechanisms alone; if approved, KP415 has the potential to be one of the first differentiated products launched in the ADHD market in some time
- Market research cites that 60% of prescribers saw KP415's potential duration of action as a key advantage. This was ranked in front of abuse potential (52%) and early onset of action (43%)
- Market research cites that prescribers estimate that ~60% of the time, methylphenidate is given as the preferred first line of therapy for children under the age of 13

(1) Source: Symphony Health, PHAST 2016

KP484: Adult ADHD Market Dynamics

- It is estimated that 4.4% of adults in the U.S. have ADHD[3]
- When applied to the full U.S. adult population aged 18 and over, there are potentially 10.5 million adults in the U.S. with ADHD[2]
- If approved, KP484 would launch into the high growth adult ADHD market.
  - Over the last seven (7) years the adult market has grown at 11% YoY vs 4% for the pediatric market[3]
  - Adults are now the largest part of the ADHD market, comprising 53% of total TRx. In 2009, adults contributed 42% of total TRx[4]
  - Despite the rapid growth in the adult market, manufacturers continue to address unmet needs for children. The last 7 products launched in the ADHD space have been pediatric focused[5]
  - Vyvanse™, the product known for its duration & ADF has seen significant growth in the adult market averaging 22% YoY growth since 2009[6]

Adult sales of Vyvanse™ are trending to surpass Pediatric sales in 2017

KP484: Adult ADHD Market Dynamics, cont.

- There is an estimated 38MM patients on ADHD medications, of which ~9% are taking an ER+ER and 10% are ER+IR[7]
  - A once daily dose could eliminate the need for multiple drugs, potentially improving adherence & reducing patient OOP costs (single copay)
- It is estimated that Shire's SXR amphetamine-based MYDAYIS™ will have >$1.5B in sales over the next six (6) years, with sales projected at $416MM in 2022[8]
  - This launch may help build awareness for once a day ADHD treatments
- The most frequently mentioned unmet need in the ADHD space is duration of action (per approximately two-thirds of prescribers surveyed)
- Per market research, nearly one third of prescribers (31%) are very or extremely concerned with the potential abuse/misuse of stimulant based therapies

KP484: Other Potential Indications

KP484 could provide the potential for other indications that have either been demonstrated by other stimulants or are unmet medical needs including:

1. Binge Eating Disorder (Vyvanse™)
2. Excessive Daytime Sleepiness (various modafinil products)
3. Stimulant dependence
4. Adjunctive therapy for other co-morbid CNS diseases

KemPharm Clinical Product Pipeline

Category	Product Candidate	Parent Drug	Development Status	Next Milestone	Potential NDA Submission
ADHD (Pediatric)	KP415	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2018
ADHD (Adult)	KP484	Methylphenidate (ER)	Clinical	PK + Efficacy Data	2019
PAIN	KP201/IR	Hydrocodone	Clinical	IN HAL Data	2018 with Priority Review
	KP511/ER	Hydromorphone	Clinical	POC in ER Formulation	2019 with Priority Review
	KP511/IR	Hydromorphone	Clinical	HAL and BE Data	2019 with Priority Review

Expected ADHD Pipeline Milestones

	Product	Event
2017	KP415	Report Additional PK Data (2H)
	KP415	Initiate Pivotal Efficacy Trial (2H)
	KP484	IND Filing (3Q)
	KP415 / KP484	IV Human Abuse Liability Data (2H)
2018	KP415	Pivotal Efficacy Trial Results (1H)
	KP484	Initiate Efficacy Studies
	KP415 / KP484	Oral and IN HAL Data
	KP415	NDA Submission
2019	KP484	Clinical Trial Program Execution / Completion
	KP484	NDA Submission


KemPharm
ADHD Prodrug Pipeline Update
June 28, 2017

KP484 Market Dynamics: 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
(3) Symphony Health, PHAST 2011-2016
(4) Symphony Health, PHAST 2011-2016
(5) Data on File
(6) Symphony Health, PHAST 2011-2016
(7) Symphony Health Transactional Data, Jun-Aug 2015
(8) Evaluate Pharma, SHP465 Worldwide Report 2017