UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

	FORM 8-K	
	CURRENT REPORT	
Pursuant to	o Section 13 or 15(d) of the Securities Exchange A	Act of 1934
Date of R	teport (Date of Earliest Event Reported): August	12, 2021
(Ex	KemPharm, Inc. Kact Name of Registrant as Specified in Its Charte	er)
Delaware (State or Other Jurisdiction of Incorporation)	001-36913 (Commission File Number)	20-5894398 (IRS Employer Identification No.)
1180 Celebration Boulevard, Suite 103, Celebration, FL (Address of Principal Executive Offices)		34747 (Zip Code)
Registrant	's Telephone Number, Including Area Code: (321)) 939-3416
(Former	Name or Former Address, if Changed Since Last	t Report)
Check the appropriate box below if the Form 8-K filing is int General Instructions A.2. below):	ended to simultaneously satisfy the filing obligatio	on of the registrant under any of the following provisions (see
☐ Written communications pursuant to Rule 425 under the S	Securities Act (17 CFR 230.425)	
□ Soliciting material pursuant to Rule 14a-12 under the Exc	change Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rule 14	d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13a	e-4(c) under the Exchange Act (17 CFR 240.13e-4(c	c))
Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KMPH	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Indicate by check mark whether the registrant is an emerging g the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapte Emerging growth company □ If an emerging growth company, indicate by check mark if the accounting standards provided pursuant to Section 13(a) of the	er). e registrant has elected not to use the extended tran	

Item 2.02 Results of Operations and Financial Condition.

On August 12, 2021, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its financial results for the second quarter ended June 30, 2021, as well as information regarding a conference call and live audio webcast with slide presentation to discuss its financial results and recent business developments scheduled for Thursday, August 12, 2021 at 4:30 p.m. ET. A copy of the press release and presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The information contained in the press release and presentation, furnished as Exhibit 99.1 and Exhibit 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 Securities 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

Description
Press Release titled "KemPharm Reports Second Quarter 2021 Financial Results" dated August 12, 2021.
Presentation titled "Second Quarter 2021 Results" dated August 12, 2021.
1 resentation titled Second Quarter 2021 Results dated August 12, 2021.

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: August 12, 2021 By: \(\frac{ls/R. LaDuane Clifton}{} \)

R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary and Treasurer



KemPharm Reports Second Quarter 2021 Financial Results

Corporate and Regulatory Highlights

- U.S. Commercial Launch of AZSTARYS™ Initiated on July 21, 2021
- Serdexmethylphenidate (SDX) Classified as a Schedule IV Controlled Substance by the DEA
- Announced Orange Book Listing for Six Patents Covering SDX and Confirmation of NCE Status
- KemPharm Added to Russell 2000® and Russell 3000® Indexes

Financial Highlights

- Q2 2021 net income of \$0.18 per basic share
- Reported Q2 2021 revenue of \$12.0 million
- Confirmed receipt of \$10 million milestone payment for DEA scheduling of SDX
- Total cash and cash equivalents was \$132.3 million at June 30, 2021

Celebration, FL – **August 12, 2021** – KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today reported its financial results for the second quarter ended June 30, 2021.

"The second quarter of 2021 and recent weeks continued what has been a period of unprecedented growth and opportunity for KemPharm, highlighted by the U.S. commercial launch of AZSTARYS," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "AZSTARYS, previously KP415, was conceived based on the vision that our LAT® technology was well-suited to developing a prodrug of d-methylphenidate (d-MPH) that could address key patient and prescriber demands that were underserved by ADHD products on the market at the time. Today that vision is a reality, and as the commercial rollout of AZSTARYS by Corium continues, ADHD patients and their caregivers will have the opportunity to benefit from the unique attributes inherent only to AZSTARYS. It is a truly exciting time for KemPharm and, we believe, for the millions of patients seeking a better treatment option for their ADHD symptoms."

Dr. Mickle continued, "In addition to the commercial launch of AZSTARYS, the second quarter was highlighted by the classification of serdexmethylphenidate (SDX) as a Schedule IV controlled substance by the Drug Enforcement Administration (DEA). SDX comprises 70% of the active pharmaceutical ingredient (API) in AZSTARYS, which is classified as a Schedule II controlled substance. Importantly, the classification of SDX as a Schedule IV controlled substance and the unique properties of SDX, we believe, provide us the opportunity to develop an SDX-based product candidate or candidates that could potentially address disease indications for which no therapy currently exists. We have recently initiated a clinical trial with SDX, and in the coming months we expect to report clinical data together with an SDX development plan. Based on the results of the clinical trial, this plan may involve one or more potential product candidates that have the potential to generate substantial near-term and longer-range value for the Company."

Q2 2021 Financial Results:

For Q2 2021, KemPharm reported revenue of \$12.0 million, which was comprised of a \$10.0 million milestone payment earned upon the DEA scheduling of SDX, and service fee revenue of \$2.0 million, as compared to Q2 2020 revenue of \$6.9 million, which was derived primarily from a \$5.0 million milestone payment earned upon U.S. Food and Drug Administration (FDA) acceptance of the AZSTARYS New Drug Application (NDA) and service fee revenue. The service fee revenue is being earned under consulting arrangements which contractually continue through March 2022.

KemPharm's net income for Q2 2021 was \$6.2 million, or \$0.18 per basic share. Recognition of a non-cash deemed dividend of \$16.9 million related to the warrant exercise inducement transaction in June 2021 led to a (\$10.7) million net loss attributable to common stockholders and diluted shares, or (\$0.40) per basic share attributable to common stockholders and diluted share for Q2 2021, compared to net income of \$0.9 million, or \$0.21 per basic and diluted share for the same period in 2020. Net income for Q2 2021 was driven primarily by operating income of \$5.8 million and a non-cash gain on extinguishment of debt of \$0.8 million related to the forgiveness of the PPP loan, partially offset by non-cash fair value adjustment loss of \$0.4 million related to derivative and warrant liability. The net operating income of \$5.8 million for Q2 2021 was a change of \$3.2 million compared to net operating income of \$2.6 million in the same period in 2020, which was primarily due to an increase in revenue of \$5.1 million and a net increase in operating expenses of \$1.8 million period over period. The net increase in operating expenses was primarily due to increases in research and development expense of \$0.9 million, general and administrative expenses of \$0.6 million and royalty and direct contract acquisition costs of \$0.4 million.

As of June 30, 2021, total cash and cash equivalents was \$132.3 million, which was an increase of \$56.4 million compared to March 31, 2021.

As of June 30, 2021, total shares of common stock outstanding was 34,977,923 shares, and fully diluted common shares outstanding was 46,546,998 shares, which included 4,584,889 shares issuable upon exercise of warrants. In addition, no preferred stock is outstanding as of June 30, 2021.

Conference Call Information:

KemPharm will host a conference call and live audio webcast on Thursday, August 12, 2021, at 4:30 p.m. ET, to discuss its corporate and financial results for Q2 2021.

Telephone Access:To access the conference call telephonically, interested participants and investors are required to register via the following online form: http://www.directeventreg.com/registration/event/2069253

Once registered, all individuals will be provided with participant dial-in numbers, a passcode and a registrant ID, which can then be used to access the conference call.

Participants may register at any time. It is recommended that the registration process be completed at least 15 minutes prior to the start of the call.

Webcast Access: The live audio webcast with slide presentation will be accessible via the Investor Relations section of KemPharm's website, http://investors.kempharm.com/. An archive of the webcast and presentation will be available for 90 days beginning at approximately 5:30 p.m. ET, on August 12, 2021.

About AZSTARYSTM:

AZSTARYS is an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years or older. AZSTARYS consists of SDX, KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH.

The complete approved prescribing information for AZSTARYS may be downloaded in PDF format here:

https://kempharm.com/wp-content/uploads/2021/03/AZSTARYS-Master-Label-Final 20210302.pdf

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT® (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT® technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, stimulant use disorder (SUD) and CNS rare diseases, including idiopathic hypersomnia (IH). KemPharm's lead clinical development candidate for the treatment of SUD, KP879, is based on its prodrug of d-methylphenidate, known as serdexmethylphenidate (SDX). In addition, KemPharm has received FDA approval for AZSTARYSTM, a new once-daily treatment for ADHD in patents age six years and older, and for APADAZ®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com or connect with us on Twitter, LinkedIn, Facebook and YouTube.

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. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements, including the potential benefits of AZSTARYS, and the potential commercial success of AZSTARYS, 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. Risks concerning KemPharm's business are described in detail in KemPharm's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and KemPharm's other filings 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.

KemPharm Contacts:

Jason Rando / Maureen McEnroe Tiberend Strategic Advisors, Inc. (212) 375-2665 / 2664 jrando@tiberend.com mmcenroe@tiberend.com

KEMPHARM, INC. UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three months ended June 30,			Six months ended June 30,			
		2021		2020	2021		2020
Revenue	\$	11,986	\$	6,908	\$ 24,103	\$	8,997
Operating expenses:							
Royalty and direct contract acquisition costs		1,000		642	2,000		1,305
Research and development		2,848		1,954	5,113		4,080
General and administrative		2,305		1,719	4,197		3,964
Severance expense							830
Total operating expenses		6,153		4,315	11,310		10,179
Income (loss) from operations		5,833		2,593	 12,793		(1,182)
Other income (expense):							
Gain (loss) on extinguishment of debt		789		_	(16,096)		_
Interest expense related to amortization of debt issuance costs and discount		_		(574)	(150)		(1,145)
Interest expense on principal		(16)		(1,197)	(215)		(2,457)
Fair value adjustment related to derivative and warrant liability		(394)		(3)	(424)		72
Interest and other (expense) income, net		(9)		40	(1)		(183)
Total other income (expense)		370		(1,734)	 (16,886)		(3,713)
Income (loss) before income taxes		6,203		859	(4,093)		(4,895)
Income tax benefit (expense)					 		_
Net income (loss)	\$	6,203	\$	859	\$ (4,093)	\$	(4,895)
Deemed dividend		(16,898)			 (54,342)		_
Net (loss) income attributable to common stockholders	\$	(10,695)	\$	859	\$ (58,435)	\$	(4,895)
Basic net income (loss) per share of common stock:							
Net income (loss)	\$	0.18	\$	0.21	\$ (0.17)	\$	(1.41)
Net (loss) income attributable to common stockholders	\$	(0.40)	\$	0.21	\$ (2.42)	\$	(1.41)
Diluted net income (loss) per share of common stock:							
Net (loss) income attributable to common stockholders	\$	(0.40)	\$	0.21	\$ (2.42)	\$	(1.43)
Weighted average number of shares of common stock outstanding:							
Basic		29,174,565		3,947,656	24,187,484		3,476,107
Diluted		29,174,565		3,947,728	24,187,484		3,476,107

KEMPHARM, INC. CONDENSED BALANCE SHEETS

(in thousands, except share and par value amounts)

		June 30, 2021 (unaudited)		December 31, 2020
Assets		(unadarca)		
Current assets:				
Cash and cash equivalents	\$	132,295	\$	4,213
Accounts and other receivables		1,888		2,579
Prepaid expenses and other current assets		1,998		1,481
Restricted cash		_		109
Total current assets		136,181		8,382
Property and equipment, net		992		1,039
Operating lease right-of-use assets		1,187		1,350
Other long-term assets		437		438
Total assets	\$	138,797	\$	11,209
Liabilities and stockholders' equity (deficit)				
Current liabilities:				
Accounts payable and accrued expenses	\$	2,973	\$	6,647
Current portion of operating lease liabilities		342		327
Current portion of loans payable		_		390
Other current liabilities		2,644		172
Total current liabilities		5,959		7,536
Convertible notes, less current portion, net		_		67,658
Derivative and warrant liability		728		304
Operating lease liabilities, less current portion		1,413		1,587
Loans payable		_		391
Other long-term liabilities		34		145
Total liabilities		8,134		77,621
Commitments and contingencies (Note D)				
Stockholders' equity (deficit):				
Undesignated preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2021 (unaudited); 9,961,846 shares authorized, no shares issued or outstanding as of December 31, 2020		_		_
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 34,977,923 shares issued and outstanding as of June 30, 2021 (unaudited); 4,537,321 shares issued and outstanding as of December 31, 2020		3		0
Additional paid-in capital		393,227		192,062
Accumulated deficit		(262,567)		(258,474)
Total stockholders' equity (deficit)		130,663		(66,412)
Total liabilities and stockholders' equity (deficit)	\$	138,797	\$	11,209



Second Quarter 2021 Results

August 12, 2021

Trademarks referenced herein are held by their respective owners.

Cautionary Note Regarding Presentation Information

This presentation 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, including without limitation 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. Forward-looking statements are not guarantees of future actions or performance. These forwardlooking statements include statements regarding the expansion of the commercial launch of AZSTARYS™, the market outlook for AZSTARYS, potential regulatory and sales milestone and royalty payments pursuant to the License Agreement with an affiliate of Gurnet Point Capital, the potential benefits of AZSTARYS, the clinical development and timing of trials and data for KP879, the potential benefits of SDX being classified as a Schedule IV controlled substance, and KemPharm's forecasted cash runway. 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. Risks concerning KemPharm's business are described in detail in the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2020, KemPharm's Quarterly Report for the quarter ended March 31, 2021, and KemPharm's other filings 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.

This presentation also may contain 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.



Q2 2021 Results Call Participants

- Travis Mickle, Ph.D. President & Chief Executive Officer
- R. LaDuane Clifton, CPA Chief Financial Officer, Secretary & Treasurer



KemPharm: Recent Highlights

AZSTARYSTM

- Commercial launch on July 21, 2021
- Expect royalties and sales milestones in 2022 and beyond
- Royalty rates on U.S. net sales of high single digits up to mid-twenties
- AZSTARYS patents extend to 2037

Solid Financial Position

- Cash on hand as of Jun 30, 2021 = \$132.3M
- Q2 2021 net income of \$6.2M, or \$0.18 per basic share
- Combination of AZSTARYS-related regulatory milestones and June warrant transaction bolstered cash reserves

SDX Schedule IV Classification

- SDX classified as Schedule IV Controlled Substance by the DEA
- HHS and DEA determined that SDX has generally low potential for abuse and a lower potential for abuse compared to d-MPH
- Key differentiator for AZSTARYS¹, and all other SDX-based product candidates

Beyond AZSTARYS

- Initiated clinical trial with SDX, with data expected prior to year-end 2021
- KVK-Tech preparing to expand Sure Med collaboration for APADAZ[®], Perspectives in Care[™], into additional regions

¹ AZSTARYS is a Schedule II controlled substance which contains SDX, a Schedule IV prodrug of d-methylphenidate



ASTARYS™ - U.S. Commercial Launch

- ✓ On July 21, 2021, Corium, Inc. initiated U.S. commercial launch of AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate capsules, CII)
 - Consists of serdexmethylphenidate (SDX), KemPharm's prodrug of dmethylphenidate (d-MPH), co-formulated with immediate-release d-MPH
- ✓ AZSTARYS Commercial Launch is a Significant Milestone for KemPharm
 - Demonstrates value potential of SDX and KemPharm's LAT® platform
 - License Agreement with an affiliate of GPC provides significant economic benefits to KemPharm tied to the commercialization of AZSTARYS
- ✓ Approved label for AZSTARYS and SDX DEA Schedule IV classification provides significant differentiation
 - The totality of various label elements, including administration, height and weight data from the clinical trials, pharmacokinetics and efficacy data, all show potential differentiation as compared to currently available d-MPH products for ADHD
 - The API in AZSTARYS (a CII controlled substance) is comprised of 70% SDX, which is classified as a CIV controlled substance, potentially increasing the appeal of AZSTARYS among prescribers and patients



AZSTARYS™ Commercialization Update

- AZSTARYS launched July 21st, 2021
- Initially a focused launch in a few states with select prescribers
- Payor discussions ongoing
 - o Typical game with all new products: Initial NCD blocks and resistance
 - Some payors have indicated initial receptivity to AZSTARYS and the differentiation that it may provide for patients
- When appropriate, the focused launch will expand
- Based on the approval label for AZSTARYS, we believe peak market share may be greater than original internal forecasts
 - o This potential was the basis for the license agreement amendment



Serdexmethylphenidate (SDX) Opportunity

- SDX provides an opportunity to explore indications outside ADHD
 - SDX is the only C-IV methylphenidate product; all others are C-II
 - SDX has a unique pharmacokinetic profile allowing for gradual and continuous release throughout the day
 - No generic equivalent and is not substitutable
- Recently initiated a trial with SDX under the KP879 IND exploring the pharmacokinetics, safety and exploratory effects of SDX at doses above those studied with AZSTARYS (>240 mg)
 - Difficult trial enrollment and retention due to nature of the study and the subjects involved
 - Data release should be available prior to year-end 2021
- Goal is to assess the best potential clinical path with SDX in future drug development in such indications like SUD, IH and others
- Provide additional clarification as to the potential development of SDX in the near-future



Financial Update



Q2 2021 Financial Results

- Revenue of \$12.0M, comprised of \$10.0M milestone payment for DEA scheduling of SDX, and service fee revenue of \$2.0M
- Net income of \$6.2M, or \$0.18 per basic share, compared to net income of \$0.9M, or \$0.21 per basic share and diluted share for Q2 2020
 - Operating income of \$5.8M and non-cash gain of \$0.8M from the forgiveness of the PPP loan during Q2 2021
 - Net loss attributable to common stockholders for Q2 2021 was (\$0.40) per basic and diluted share, driven by a <u>non-cash</u> deemed dividend of \$16.9M related the warrant exercise inducement transaction in June
- Operating income increased \$3.2M, primarily driven by an increase in revenue of \$5.1M, partially offset by a net increase in operating expenses of \$1.8M as compared to Q2 2020
 - R&D expenses were \$2.8M, an increase of \$0.9M vs. Q2 2020
 - G&A expenses were \$2.3M, an increase of \$0.6M compared to Q2 2020



Q2 2021 Balance Sheet Update

- As of June 31, 2021, total cash was \$132.3M, an increase of \$56.3M compared to Mar 31, 2021, primarily due to receipt of \$20M in cash milestones related to AZSTARYS, and \$40.6M in proceeds from warrant exercises during Q2 2021
- Completed warrant exercise inducement transaction in June 2021:
 - Received \$39.1M of gross proceeds from the exercise of 6,117,509 existing warrants at exercise price of \$6.36 per share
 - o Issued 1,529,379 inducement warrants with an exercise price of \$16.50
- As of June 30, 2021:
 - o 34,977,923 common shares outstanding
 - 46,546,998 fully diluted shares outstanding, which includes 4,584,889 of shares issuable upon exercise of warrants
 - No preferred stock outstanding



Solid Financial Position

- KemPharm's balance sheet has been completely restructured and recapitalized with a cash balance that provides for:
 - operating requirements,
 - o internal development opportunities, and
 - o other potential external investments
- Shelf registration on Form S-3 is just another component of the financial restructure process, a "housekeeping" step; no immediate needs, but available if strategically appropriate in the future
 - ATM agreement is another housekeeping tool (maintained by most life science companies); reserved for opportunistic use only if needed
 - Formalizes ongoing relationship with investment banks
- Taken together, our goal through these steps has been to provide for an extended cash runway and to enable greater operating and strategic flexibility



KemPharm: Looking Ahead

AZSTARYSTM

- U.S. commercial rollout is being led by Corium and is progressing as planned
- KemPharm continues to support manufacturing, scientific and regulatory affairs
- Expect royalties and sales milestones in 2022 and beyond

Improved Financial Position

- Cash on hand as of June 30, 2021 = \$132.3M
- Tools in place to enable operating and strategic flexibility
- Looking forward to the potential of licensing revenue from AZSTARYS royalties and sales milestones

SDX Opportunity

- Clinical trial with SDX underway
- Multiple potential paths forward will be fully explored with clinical data and commercial potential

Beyond AZSTARYS

- Continued evaluation of pipeline and other external opportunities
- Upcoming clinical data from SDX clinical trials, and initial SDX development plan





Second Quarter 2021 Results

August 12, 2021