# 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): August 11, 2022	
KemPharm, Inc.	
(Exact Name of Registrant as Specified in Its Charter)	
001-36913	20-5894398
(Commission File Number)	(IRS Employer Identification No.)
	34747
	(Zip Code)
Registrant's Telephone Number, Including Area Code: (321) 939-3416	

Delaware (State or Other Jurisdiction of Incorporation)

1180 Celebration Boulevard, Suite 103, Celebration, FL (Address of Principal Executive Offices)

(Former Name or Former Address, if Changed Since Last Report)

Che	ck 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))

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, par value \$0.0001 per share	КМРН	The Nasdaq Stock Market LLC
		(Nasdaq Global Select Market)

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  $\ \square$ 

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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On August 11, 2022, KemPharm, Inc., a Delaware corporation, or KemPharm, issued a press release announcing its financial results for the second quarter ended June 30, 2022, as well as information regarding a conference call and live audio webcast with slide presentation to discuss its financial results and corporate updates scheduled for Thursday, August 11, 2022 at 5:00 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

Exhibit No.	Description
99.1	Press Release dated August 11, 2022,
99.2	Presentation dated August 11, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## 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 11, 2022

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



#### KemPharm Reports Second Quarter 2022 Financial Results and Corporate Updates

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today, August 11, 2022, at 5:00 p.m. ET

Perry Sternberg, Corium, Inc.'s President and CEO, to Participate and Provide Update on the Commercialization of AZSTARYS®

- Acquired substantially all the assets and operations of Orphazyme A/S, including arimoclomol, for a cash payment of \$12.8 million
- Resubmission of the arimoclomol NDA for the treatment of NPC as early as Q1 2023
- Filed IND application for KP1077, an SDX-based product candidate for the treatment of IH
- Initiation of a Phase 2 trial (KP1077.D01) expected by the end of 2022
- Topline data from Phase 1 clinical trial evaluating cardiovascular safety of SDX expected as early as Q3 2022
- Total cash, cash equivalents and investments were \$114.5 million as of June 30, 2022

Celebration, FL – August 11, 2022 – KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a specialty pharmaceutical company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS), neurodegenerative and lysosomal storage diseases, today reported its financial results for the second quarter ended June 30, 2022.

"KemPharm's recent acquisition of arimoclomol, along with substantially all of Orphazyme's assets and operations, provided an exclamation point to the first half of 2022 as we shifted our strategic focus to the development of therapies targeting rare central nervous system (CNS), neurodegenerative, and lysosomal storage diseases," stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "We believe this orientation towards rare disease classification with limited treatment options, and no approved treatments in the U.S. provides a significant opportunity for KemPharm to make an impact in an area of high-need and to validate the potential of our strategy to create both near and longer-term shareholder value."

Dr. Mickle continued, "The acquisition of arimoclomol is a unique and potentially game-changing opportunity for KemPharm. Arimoclomol is an NDA-stage product candidate being developed for the treatment of Niemann-Pick disease type C (NPC), a rare neurodegenerative disease for which no approved therapy exists in the U.S. We acquired this asset for total consideration of \$18.0 million, which included a cash payment of \$12.8 million and the assumption of an estimated reserve liability equal to approximately \$5.2 million. The cash payment was funded through a line of credit secured by our balance sheet, making this transaction very capital efficient. Another important part of this transaction is maintaining the early access programs in the U.S. and the E.U. while we support the ongoing work of seeking regulatory approval. KemPharm is concentrating more of our resources towards the resubmission of the arimoclomol NDA with the U.S. Food and Drug Administration (FDA), which we expect to complete as early as the first quarter of 2023."

Dr. Mickle continued, "In parallel with our work on arimoclomol is the ongoing development of KP1077, our lead clinical candidate, which we are advancing as a treatment for idiopathic hypersomnia (IH) and narcolepsy. As announced in May, the Investigational New Drug (IND) application to initiate a clinical program investigating KP1077 for the treatment of IH has been successfully filed with the FDA. We expect to initiate the Phase 2 trial of KP1077 in IH by the end of 2022, with a second trial focused on narcolepsy commencing soon thereafter. Additionally, we expect to report topline results from the cardiovascular safety study involving serdexmethylphenidate (SDX) as soon as Q3 2022. We believe that demonstrating an improved cardiovascular safety profile compared to current stimulants could be a key potential differentiator for KP1077."

Dr. Mickle continued, "The execution of our strategy is continuing as KemPharm seeks to build a diverse and unique product portfolio combining an NDA-stage product with a rapidly advancing clinical-stage pipeline targeting multiple disease indications. Additionally, KemPharm continues to be excited by the commercialization of AZSTARYS® by Corium. We are pleased that Perry Sternberg, Corium's President and CEO, will join our second quarter results conference call to discuss ongoing commercialization activities and review the substantial progress made, including the recent national expansion of the launch of AZSTARYS."

Dr. Mickle concluded, "Looking ahead, we believe KemPharm is well positioned for growth on multiple fronts, while possessing a strong operational and financial foundation, including \$114.5 million in cash, cash equivalents and investments as of June 30, 2022. We believe these attributes, combined with the numerous milestone opportunities anticipated for 2022 and beyond, position KemPharm for continued growth despite current macroeconomic and global equity market challenges. This is a very exciting time for KemPharm."

#### O2 2022 Financial Results:

KemPharm's net revenue for Q2 2022 was \$1.3 million, as compared to Q2 2021 net revenue of \$12.0 million. The Q2 2021 net revenue included a one-time regulatory payment of \$10 million for the DEA scheduling of AZSTARYS.

Research and development expenses were \$4.8 million for Q2 2022, as compared to \$2.8 million in Q2 2021, driven primarily by spending on the KP1077 clinical development program and, increased compensation costs, including non-cash stock-based compensation expense.

General and administrative expenses were \$3.6 million for Q2 2022, as compared to \$2.3 million in Q2 2021. The period-over-period increase was primarily driven by increased compensation costs, including non-cash stock-based compensation expense.

In addition, KemPharm recognized \$17.7 million of expense during Q2 2022 related to acquired in-process research and development from the arimoclomol asset acquisition during the quarter, which was immediately expensed.

Net loss attributable to common stockholders for Q2 2022 was (\$24.0) million, or (\$0.70) per basic and diluted share, compared to a net loss attributable to common stockholders of (\$10.7) million, or (\$0.40) per basic and diluted share for the same period in 2021. Net loss for Q2 2022 was driven primarily by the one-time non-cash expense recognized in Q2 2022 for the arimoclomol asset acquisition of \$17.7 million, research and development expense of \$4.8 million, and general and administrative expense of \$3.6 million, partially offset by an income tax benefit of \$0.7 million. Excluding the one-time \$17.7 million of non-cash expense related to the arimoclomol asset acquisition recognized during Q2 2022, adjusted net loss was (\$6.4) million, or (\$0.19) per basic and diluted share.

#### Conference Call Information:

KemPharm will host a conference call and live audio webcast with a slide presentation today at 5:00 p.m. ET, to discuss its corporate and financial results for the second quarter of 2022.

The audio webcast with slide presentation will be accessible via the Investor Relations section of the Company's website, http://investors.kempharm.com/. An archive of the webcast and presentation will be available for 90 days beginning at approximately 6:00 p.m. ET, on August 11, 2022.

Additionally, interested participants and investors may access conference call by dialing either:

- (800) 245-3047 (U.S.) (203) 518-9765 (International) Conference ID: KMPHQ222

#### About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS), neurodegenerative and lysosomal storage diseases. KemPharm has a diverse product portfolio, combining a clinical-stage development pipeline with NDA-stage and commercial assets. The pipeline includes arimoclory, development pipeline with NDA-stage and commercial assets. The pipeline includes arimoclory, development pipeline with NDA-stage and commercial assets. The pipeline includes arimoclory, and carried eliverse, first-in-class investigational product candidate for Niemann-Pick disease type C (NPC), and KP1077, which the Company is developing as a treatment for idiopathic hypersonnia (IH), a rare neurological sleep disorder, and narcolepsy. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a once-daily treatment for ADHD in patients age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S., and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S. For more information on KemPharm and its pipeline of 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation and which can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "could," "intend," "target," "predict," or the negative versions of those words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding the promise and potential impact of our preclinical or clinical trial data, including without limitation the timing and results of any clinical trials or readouts, the timing or results of any IND applications and NDA submissions, including the resubmission of the NDA for arimoclomol, the potential uses or benefits of arimoclomol, KP1077, SDX or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of KemPharm's product candidates, the success or timing of the launch or commercialization of AZSTARYS or any other products or related sales milestones, the sufficiency of cash to fund operations, our plans or ability to seek funding, and our strategic and product development objectives. 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 known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of KemPha

#### **KemPharm Contacts:**

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# KEMPHARM, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except share and per share amounts)

	Three months ended June 30,		Six months er	Six months ended June 30,		
	 2022	2021	2022		2021	
Revenue, net	\$ 1,300	\$ 11,986	\$ 5,265	\$	24,103	
Operating expenses:						
Cost of revenue	51	1,000	59		2,000	
Research and development	4,795	2,848	7,877		5,113	
General and administrative	3,558	2,305	6,292		4,197	
Acquired in-process research and development	 17,663		17,663			
Total operating expenses	 26,067	6,153	31,891		11,310	
(Loss) income from operations	 (24,767)	5,833	(26,626)		12,793	
Other income (expense):						
Gain (loss) on extinguishment of debt	_	789	_		(16,096)	
Interest expense related to amortization of debt issuance costs and discount	_	_	_		(150)	
Interest expense on principal	(36)	(16)	(41)		(215)	
Fair value adjustment related to derivative and warrant liability	32	(394)	273		(424)	
Interest and other income (expense), net	 14	(9)	(231)		(1)	
Total other income (expense)	 10	370	1		(16,886)	
(Loss) income before income taxes	(24,757)	6,203	(26,625)		(4,093)	
Income tax benefit	 715		719	<u> </u>		
Net (loss) income	\$ (24,042)	\$ 6,203	\$ (25,906)	\$	(4,093)	
Deemed dividend	 	(16,898)			(54,342)	
Net loss attributable to common stockholders	\$ (24,042)	\$ (10,695)	\$ (25,906)	\$	(58,435)	
Basic and diluted net loss per share of common stock:						
Net loss attributable to common stockholders	\$ (0.70)	\$ (0.40)	\$ (0.75)	\$	(2.42)	
Weighted average number of shares of common stock outstanding:						
Basic and diluted	 34,447,206	29,174,565	34,476,737		24,187,484	

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

		June 30, 2022		December 31, 2021	
Assets					
Current assets:					
Cash and cash equivalents	\$	76,779	\$	112,346	
Short-term investments		4,199		_	
Accounts and other receivables		2,820		1,528	
Prepaid expenses and other current assets		3,637		1,182	
Total current assets		87,435		115,056	
Inventories		779			
Property and equipment, net		904		884	
Operating lease right-of-use assets		1,165		1,141	
Long-term investments		33,535		15,422	
Other long-term assets		440		438	
Total assets	\$	124,258	\$	132,941	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	3,600	\$	3,038	
Current portion of operating lease liabilities		469		356	
Current portion of discount and rebate liabilities		1,796		_	
Other current liabilities		1,294		836	
Total current liabilities		7,159		4,230	
Line of credit payable		12,800		_	
Derivative and warrant liability		57		330	
Operating lease liabilities, less current portion		1,082		1,232	
Discount and rebate liabilities, less current portion		3,900		_	
Other long-term liabilities		27		31	
Total liabilities		25,025		5,823	
Stockholders' equity:					
Stockholaers equity: Preferred stock:					
Undesignated preferred stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2022 (unaudited) or December 31, 2021		_		_	
Common stock, \$0.0001 par value, 250,000,000 shares authorized, 35,399,267 shares issued and 34,489,314 shares outstanding as of June 30, 2022 (unaudited); 35,325,801 shares issued and 35,005,640 shares outstanding as of December 31, 2021		3		4	
Additional paid-in capital		399.701		396,957	
Treasury stock, at cost		(7,536)		(2,814)	
Accumulated deficit		(292,935)		(267,029)	
Total stockholders' equity	_	99,233	_	127,118	
	\$	124,258	\$	132,941	
Total liabilities and stockholders' equity	φ	124,230	Ψ	152,541	



# **Cautionary Note Regarding Presentation Information**

This presentation may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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," "could," "intend," "target," "predict," or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding the promise and potential impact of our preclinical or clinical trial data, including without limitation the timing and results of any clinical trials or readouts, the timing or results of any IND applications, the potential uses or benefits of arimoclomol, KP1077, SDX or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of KemPharm's product candidates, the success or timing of the launch or commercialization of AZSTARYS or any other products or related sales milestones, the sufficiency of cash to fund operations, our plans or ability to seek funding, our plans with respect to our share repurchase program, and our strategic and product development objectives. 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 known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2021, as updated

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to this presentation.

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 2022 Results Call Agenda

1) Introduction Travis Mickle, Ph.D.

President and Chief Executive Officer

2) AZSTARYS® Update Perry Sternberg

President and Chief Executive Officer, Corium, Inc

3) Product Development Updates Travis Mickle

4) Financial Update R. LaDuane Clifton, CPA

Chief Financial Officer, Secretary & Treasurer

5) Question and Answer

# **AZSTARYS**®

d-Methylphenidate Prodrug Product for the Treatment of ADHD



# Corium, Inc. - AZSTARYS® Commercialization

## **End-to-End Pharma Company**

- ✓ Developing and commercializing innovative CNS therapies
- ✓ Owned by affiliate of Gurnet Point Capital
- ✓ Offices and manufacturing facility in Grand Rapids, MI and Boston, MA

## **ADHD Expertise**

✓ Led by Perry Sternberg and team with broad ADHD expertise, including former Shire executives responsible for helping Vyvanse® achieve blockbuster status



### **Commercial Focus**

- √ Two CNS product approvals in past 12 months
- ✓ AZSTARYS (March 2021) and ADLARITY® (March 2022 for Alzheimer's dementia)

## **CDMO** Capabilities

- ✓ Transdermal development and manufacturing expertise
- ✓ Developed and manufacturing several consumer and FDA approved drug products



# **AZSTARYS® Product Overview**

- Approved by the U.S. FDA in March 2021
- Indicated for the treatment of ADHD in patients 6 years of age and older
- Contains 70% prodrug of d-MPH (serdexmethylphenidate, or SDX) co-formulated with 30% immediate release d-MPH,
- · Product is a Schedule II drug, with SDX component being Schedule IV
- First and only approved methylphenidate-based drug containing SDX
- Patent protection until at least 2037



# AZSTARYS® - U.S. Commercial Launch Update

Rx Growth

- Steady growth in prescriptions during market introduction phase in both breadth and depth of prescribing
- Increasing number of pharmacies ordering AZSTARYS based on geographic areas in which Corium places sales representatives
- National Launch Progress
- Initial regional launch in 2021 and early 2022 focused on geographies with product coverage
- As of July 2022, National field team deployed comprised of ~175 field sales reps
- Held first AZSTARYS National Sales Meeting in July 2022 in connection with National launch
- Significant market access success, with coverage of almost 145 million lives and preferred status for 35 million of those covered lives

Adult ADHD Market

- · Increasing commercial team focus on adult market
- With Takeda pulling back on Vyvanse field sales promotion we are expanding call deck from just pediatric targets into adults



# KEMPHARM VALUE PROPOSITION

Innovative pharma company with a proven regulatory track record targeting rare CNS, neurodegenerative and lysosomal storage diseases

Revenue-generating assets with significant commercial potential in areas of high unmet need

Strong balance sheet which is expected to fund operations and U.S. commercial build beyond 2025

# KemPharm: Q2 2022 and Recent Highlights

- ✓ NDA-stage asset expands pipeline targeting rare orphan CNS diseases
- √ "Capital efficient" deal structure w/potential for positive cash flow, and no shareholder dilution
- ✓ Potential to re-file NDA as early as Q1 2023

Arimoclomo Acquisition KP1077 Development Program

- ✓ KP1077 IND for IH submitted to FDA
- ✓ Phase 2 trial initiation in IH in 2H 2022
- √ Cardiovascular trial initiated; topline data as early as Q3 2022

- ✓ Full national team in place; ~175 reps
- √ ~145M+ covered commercial lives; preferred status for 35 million of those covered lives
- ✓ Expanded launch of AZSTARYS supports revenue potential from royalties and milestones

AZSTARYS® National Launch Strong Balance Sheet to Support Value Creation

- Cash, cash equivalents and investments of \$114.5M as of June. 30, 2022
- ✓ Solid balance sheet supports development efforts and other pipeline expansion activities
- ✓ Available capital extends cash runway beyond 2025





# **Arimoclomol - Expanding Pipeline Targeting Rare Diseases**

Aligns with strategy to build value through the development and commercialization of novel treatments for rare diseases

# Niemann-Pick disease type C

- ✓ Ultra-rare progressive, disabling and fatal lysosomal storage disorder
- ✓ No approved treatments exist in the U.S. for NPC

### **Favorable Acquisition Terms**

√ "Capital efficient" financial structure
with potential for positive cash flow
and no shareholder dilution



## **High Upside Opportunity**

- ✓ NDA-stage investigational drug candidate
- √ KemPharm has expertise in NDA resubmissions following CRLs

### **Early Access Programs**

- ✓ Available to NPC patients in the U.S., France, Germany and other European countries
- √ French EAP expected to generate annual gross revenue of ~\$12M



# Near-Term Opportunity to Commercialize and Retain Full Market Value

Arimoclomol represents an opportunity for KemPharm to launch with a small, focused commercialization effort which can be foundation for future rare products, including KP1077

- Typically, ultra-rare disease commercial teams are less than 20 individuals which can be expanded as additional products are approved
- Lower marketing spend since population is well defined and physicians are primarily located in treatment centers
- Patient advocacy groups and relationships with treatment centers are also key drivers
- Existing network of relationships with treatment centers and physicians already participating in early access programs in the U.S. and E.U.
- Partnerships/licensing opportunities may be available in other markets (Japan, China, others)



## **KP1077 – Product Candidate Overview**

KemPharm is advancing KP1077 as a potential therapeutic treatment for Idiopathic Hypersomnia (IH)

## Serdexmethylphenidate

- √ 100% SDX with multiple dosing options
- ✓ SDX has already been designated C-IV by DEA

## Regulatory & IP Advantages

- ✓ Eligible for Fast-Track, Orphan Drug and Breakthrough Therapy designation
- ✓ Solid IP through 2037 and potentially beyond



## **Dosing Addresses Symptoms**

- ✓ Dosed either 1x daily at bedtime c 2x daily at bedtime and at waking
- √ Potential to address primary IH symptoms: sleep inertia and brain fog

## Improved Safety & Tolerability

- ✓ Greater tolerability and lower cardiovascular effects could allow for higher, more effective dosing (i.e. greater efficacy)
- ✓ No DDI potential with hormonal contraceptives; antidepressants



# Upcoming Clinical and Regulatory Milestones Create Potential Near-Term Value

Milestone	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023
Arimoclomol							
Re-file NDA for NPC							
KP1077 for IH							
Type B meeting with FDA					/		
IND filing/may proceed	✓	7					
Phase 1 CV differentiation trial	✓					7	
Phase 2 trial							
KP1077 for Narcolepsy					Va plan		
Type B meeting with FDA							
IND filing					A		
Phase 2/3 trial initiation							

Note: Blue box denotes activity timeframe





# Financial Position is a Source of Strength

### Q2 2022 Income Statement Details:

- Net revenue of \$1.3M, derived from arimoclomol product sales under the French EAP, consulting services fees and royalties
- Q2 2022 net loss attributable to common stockholders of (\$24.0M), or (\$0.70) per basic and diluted share, driven primarily by one-time non-cash expense related to the arimoclomol asset acquisition of \$17.7M
- Adjusted net loss excluding the arimoclomol asset acquisition expense is (\$6.4M), or (\$0.19) per basic and diluted share

## Balance Sheet Details as of Jun. 30, 2022:

- Cash, cash equivalents and investments were \$114.5M, a decrease of \$4.6M compared to Q1 2022
- · Line of credit for the arimoclomol acquisition expected to be serviced by the cashflow from French EAP
- · Available cash, cash equivalents and investments extends cash runway beyond 2025



